



An-Najah National University

Faculty of Graduate Studies

**THE EFFECTIVENESS OF EARLY ENTERAL
FEEDING PROTOCOL ON PRETERM
CLINICAL OUTCOMES IN NEONATAL
INTENSIVE CARE UNITS IN TWO LARGE
HOSPITALS IN JENIN**

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Dedication

I dedicate this achievement to my beautiful family, and I will start with my child and then my husband, who shared every step with me to achieve this achievement. I also want to dedicate this achievement to my parents, my mother and father, who have always supported me in every step in order to continue my successes

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I extend special thanks to everyone who helped and supported me during my career in the master's program.

Declaration

I, the undersigned, declare that I submitted the thesis entitled:

THE EFFECTIVENESS OF EARLY ENTERAL FEEDING PROTOCOL ON PRETERM CLINICAL OUTCOMES IN NEONATAL INTENSIVE CARE UNITS IN TWO LARGE HOSPITALS IN JENIN

I declare that the work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

Student's Name: Eshtyag Hatem Saleh Hamden

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Date: 8/9/2024

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**THE EFFECTIVENESS OF EARLY ENTERAL FEEDING PROTOCOL ON
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Abstract

Background: About 70% of preterm infants struggle with oral feeding due to poor motor maturity, neural pathways, respiratory and gastrointestinal system pathology, low tolerance for interaction, and unstable behavioral state organization.

Objectives: The study aims to evaluate the clinical outcomes of preterm infants receiving early enteral feeding protocols compared to those receiving standard enteral feeding protocols in NICUs.

Methodology: The study employed a quasi-experimental design comparing two groups of 45 preterm infants in each group. There was an intervention group, a control group (group C) who did not receive early enteral protocol, and an experimental group (group E) who received an early enteral feeding protocol.

Results: The results show a significant difference at the 0.05 level between the study groups (C and E) in increased weight only on the first and sixth days.

For vital signs within normal for each group, group C had a higher HR on selected days and in total compared to group E.

For laboratory values, group C had higher WBC, BUN, Na, K, albumin (only on day 5), and bilirubin than group E, which is within the normal range for these variables, and group C had lower PLT and Ca than group E, with no significant differences in HGB, CR, and glucose.

On mechanical ventilator setup, the total FiO₂ for 7 days in group C was higher than in group E, and the set rate in group C was higher than in group E. Therefore, the

percentage of babies who were extubated faster in Group E was higher than in Group C, indicating that the percentage of hospital stays for Group E was lower than for Group C by reducing the percentage of oxygen to them faster.

Conclusion: Implementing early enteral feeding protocols may lead to improved outcomes, clinical stability in preterm infants, and reduced length of stay in the hospital, contributing to enhanced overall health outcomes during their neonatal period.

Keywords: NICUs; Preterm Infants; low birth weight; early enteral feeding; late enteral feeding.

Chapter One

Introduction and Theoretical Background

1.1 Introduction

Research on preterm infants has been a tradition for a long time. In preterm infants, early enteral feeding provides essential nutrients and encourages necessary growth. Although supplying these infants with sufficient total energy and protein may frequently take precedence, supplying them with sufficient micronutrients, including 13 vitamins and various minerals, is still essential for fostering optimal physical growth and neurodevelopment. Compared to parenteral nutrition alone, early enteral feeding may significantly increase the supply of essential micronutrients through fortification or nutrient supplementation, particularly if parenteral additive shortages exist. In addition, preterm infants receiving total parenteral nutrition may not benefit sufficiently from parenteral micronutrient formulations. For example, joint guidelines for parenteral vitamin D administration range from 200–1000 International Units (IU) per day (or 80–400 IU/kg/day) (Bronsky et al., 2018; Thoene & Anderson-Berry, 2021).

A baby's birth weight of less than 2500 grams is considered to be low birth weight. Every year, more than 20 million babies are born with Low Birth Weight (LBW), and more than 96% of these babies are born in developing nations (Cutland et al., 2017; Organization, 2011; Tewoldie et al., 2022). Preterm birth (birth before 37 weeks of gestation) or small size for gestational age (birth weight below 10th percentile) can result in LBW. Nutritional care for LBW infants, especially those with birth weights between 1000 and 2000 grams, is mostly either parenteral, enteral, or a combination of the two. Most developing nations, where resources are limited, provide a maintenance fluid consisting solely of glucose and electrolytes via intravenous fluid rather than parenteral nutrition (Bora & Murthy, 2017).

Enteral nutrition can be vital for neonates in intensive care units (Hay, 2018). However, the introduction of enteral feeding early after admission to the intensive care units remains highly controversial. While some healthcare practitioners suggest that enteral feeding should be delayed as it is expected to increase the demand for oxygen by neonates, it might deteriorate the hemodynamic instability of the neonates. Additionally, it is believed that early introduction of enteral feeding could be associated with a higher risk

for multi-organ dysfunction, small bowel necrosis, necrotizing enterocolitis (NEC), and/or gastrointestinal ischemia (Dorling & Gale, 2019; Kalra et al., 2018). On the other hand, other practitioners believe that delayed enteral feeding can result in metabolic disorders, infections, and impairments to the functional adaptation of the neonatal gastrointestinal tract (Dorling & Gale, 2019; Hay, 2018; Kalra et al., 2018). Therefore, researchers and practitioners have suggested that the early introduction of small volumes of enteral feeds (trophic feeding) might improve intestinal function maturation, thus promoting tolerance of enteral feeding.

1.2 Background

Prematurity is one of the most critical child health problems, it accounts for 50% of childhood disability and is the leading cause of prenatal mortality (Del Río et al., 2020). Every year, approximately 15 million babies worldwide are born before term. Prematurity is one of the most critical child health problems because it accounts for 50% of childhood disability and is the leading cause of perinatal mortality (Del Río et al., 2020). Globally, around 20.5 million newborn infants were born with birth weights <2,500 g in 2015, 90% of whom were from low- and middle-income countries (Gu et al., 2017). This is one of the most significant issues affecting children's health, considered preterm by the World Health Organization (WHO) if it is born before 37 weeks of gestation and falls into one of the following categories based on gestational age (GA): extremely premature (less than 28 weeks gestational age), very premature (between 28 and 32 weeks), and moderate or late premature (between 32 and 37 weeks) (Brune & Donn, 2018; Vogel et al., 2016). Preterm infants require adequate nutrition for optimal health and growth.

LBW infants account for 8 percent of neonatal deaths. This category includes both preterm infants born before 37 weeks gestational age and infants who are small for gestational age (SGA) or those whose weight is below the 10th percentile for gestational age. Up to a million newborn deaths occur annually due to preterm birth, which is the single most common cause of death during the neonatal period (Blencowe et al., 2019; Liu et al., 2016). Among LBW babies, exceptionally low birth weight (VLBW; 1,000 g to 1,500 g) and very preterm babies (born 28 to 32 weeks gestational age or less) are even more at risk, with higher rates of feeding intolerance, necrotizing enterocolitis

(NEC), late-onset sepsis (LOS), and ultimately death (Athalye-Jape & Patole, 2019; Nabwera et al., 2021).

The physiological processes that would take place in utero during the third trimester of pregnancy are carried out in the neonatal intensive care unit (NICU) because the preterm baby is born at a critical time for the growth and development of the nervous system. The prevalence of preterm births is highest in South Asia. Pakistan ranks fourth among the top ten nations, with 60% of preterm births worldwide. The majority of grams is considered to be LBW (Fayyaz et al., 2020).

As many as 70% of preterm infants have difficulty with oral feeding due to poor motor maturity, underdeveloped neural pathways, pathology of the respiratory and gastrointestinal systems, low tolerance for interaction, and unstable behavioral state organization. Other complications of prematurity and low birth weight include respiratory distress syndrome, fluid and electrolyte imbalances, apnea of prematurity, intraventricular hemorrhage, patent ductus arteriosus, and poor thermoregulation (Jadcherla, 2019).

The goal of nutrients is to meet the growth rate and body composition of a normal, healthy fetus of the same gestational age. Weight, length, head circumference, organ size, tissue components, including cell number and structure, blood and tissue nutrient concentrations, and developmental outcomes are the objectives of preterm infant nutrition (Hay, 2018).

Because of health concerns that early initiation in the first days of life may lead to health complications such as necrotizing enterocolitis (NEC), which is characterized by inflammation of the gastrointestinal tract of infants and is associated with mortality and multiple morbidities, clinicians debate the optimal timing of enteral feeding for preterm and LBW infants (Shulhan et al., 2017). Infants born prematurely (less than 37 weeks) or at a low birth weight (less than 2500 grams), particularly those born very preterm (less than 32 weeks) or at a low birth weight (less than 1500 grams), have less developed organs and are more likely to develop NEC. In addition, women in communities all over the world may delay giving their children food because they want to throw away their colostrum, in pain or discomfort after giving birth, or they are

worried about the baby's maturity as a child and whether or not it can digest milk (Mukunya et al., 2017).

The provision of nutrients that are not considered vital to life but have the potential to affect health is another advantage of early enteral feeding. One example of a non-essential micronutrient found in human milk or infant formula is carotenoids like lutein, which concentrate in the tissue of the brain and eyes at levels that vary depending on dietary intake (Thoene & Anderson-Berry, 2021).

A feeding tube is a small, flexible plastic tube inserted into the stomach through the nose (NG) or mouth (OG). Until the baby can take food by mouth, medicines and feedings are delivered through these tubes into the stomach. A feeding tube (FT) is frequently required for babies in the neonatal intensive care unit (NICU). Feeding tubes are close to formula or human milk all the time, providing ample nutrition for consumption. A feeding tube is used because strength and coordination are required for bottle or breastfeeding. It is possible that premature or sick babies will not be able to swallow or suck well enough to bottle or breastfeed. The baby can get some or all of their food into their stomach through tube feeding. This is the most productive and most secure method for giving great sustenance. The tube can also be used to administer oral medications. A feeding tube is positioned by gently inserting it into the stomach through the nose or mouth.

An X-ray can verify the correct position. The tube tip can be inserted into the small intestine past the stomach in babies with feeding issues. This method provides slower, continuous feedings. However, a feeding tube can pose several dangers, such as infection, tube displacement, and nasal or oral passage irritation. Most of the time, feeding tubes work well and are safe. However, issues may still arise if the tube is positioned correctly. These are some minor bleeding from irritation of the nose, mouth, or stomach; stuffy or infected nose if the tube is inserted through the nose. If the tube is misplaced or not in the right position, the baby may experience issues with a heartbeat that is too slow (bradycardia) and Breathing (Kaneshiro, 2022; Poindexter & Martin, 2019).

Formulas specifically designed for premature infants exist. They supply most of the baby's nutritional requirements. Formulas made of soy protein should not be given to premature infants. After birth, a premature infant has higher energy demands than usual. The baby may require a high-calorie supplement for optimal growth and healing, regardless of how they are fed (Moreira-Monteagudo et al., 2022).

Preterm formula—also known as "preterm formula"—has a higher concentration of nutrients than term formula, such as minerals, protein, and most vitamins, and is specifically made to support premature babies' growth and development. Preterm formula also contains a lot of calcium and phosphorus to help bones grow (Franck et al., 2020).

American Academy of Pediatrics recommends starting enteral feedings within the first 12 to 24 hours of life for stable infants and as soon as possible for unstable infants. The WHO suggests starting with EFin the first hour of life for stable infants and as quickly as possible for unstable infants to reach full enteral feeds in the first week of infancy.

Walsh et al. (2020) did a systematic review to identify the outcome of initiating early EF against delayed EF among preterm. Findings found that infants who received early EF had more satisfactory outcomes than the other delayed group regarding mortality rate, duration of hospitalization, sepsis, and NEC, but in other parameters not specific, such as intraventricular hemorrhage and head circumference.

Delaying internal feeding in newborns can lead to changes in the mucosal crypt-villus axis, increasing the risk of bacterial translocation and infections. Unintentionally, prolonged periods without enteral feeding can cause gastrointestinal mucosa damage. Interrupting feeding can prevent feeding intolerance during treatment, post-NEC diagnosis, or in infants recovering from surgery. A recent systematic review found a lower incidence of recurrent NEC and post-NEC stricture among infants who resumed enteral feedings sooner (Bjornvad et al., 2005; Siggers et al., 2011; Kennedy & Tyson, 2000; Shen et al., 2015). Early and aggressive nutritional support, both enteral and parenteral, can improve growth and developmental outcomes in preterm LBW infants. Increased protein and energy intake during the first week after birth leads to higher IQ scores, enhanced cognitive function, and faster head growth (Leppänen et al., 2014).

Algarra et al. (2017) investigated the variability in enteral feeding practices for very low birth weight (VLBW) neonates within the SEN-1500 Spanish network. An observational study using a 2013 questionnaire revealed that 67% of hospitals had feeding protocols, yet 52% experienced variability within their units. Only 25% of units had access to milk banks. The timing of the first feeding varied, often delayed in lower gestational age neonates due to hemodynamic instability and lack of breast milk. Half of the units with neonates under 25 weeks started with progressive feeding increases rather than trophic feeding. Feeding volumes rarely exceeded 30 mL/kg/day, but most units used fortifiers, vitamins, and probiotics. The study highlighted significant variability in enteral nutrition policies, emphasizing the need for evidence-based protocols and improved access to donor milk to reduce necrotizing enterocolitis (NEC) and enhance nutritional outcomes.

A study by Morgan et al. (2019) compared the impact of delayed initiation of progressive enteral feeds on the incidence of necrotizing enterocolitis (NEC) and mortality in very preterm or VLBW infants. The researchers found that infants in this group took longer to achieve full enteral feeding than those with early introduction. A study by Nangia et al. (2019) found that early total enteral feeding (ETEF) achieved full feeds earlier than conventional enteral feeding (CEF) in stable VLBW infants, with no significant difference in NEC incidence. Leaf et al. (2012) found that early initiation of enteral feeding in growth-restricted preterm infants led to earlier achievement of sustained full enteral feeding without increasing the risk of NEC.

In addition, a systematic review by Perez et al. (2023) found that early progressive feeding does not increase the risk of NEC and that rapid progression of feeding and early establishment of full enteral feeding in VLBW infants is feasible without increasing the risk. The results of the Fluids Exclusively Enteral From Day 1 (FEED 1) trial and the Early, Exclusive, Enteral Nutrition (E3NACT) trial are expected to enhance feeding practices and nutrition for VLBW infants. Chitale and colleagues (2022) found that early enteral feeding initiation in preterm infants decreases mortality, hospitalization duration, and sepsis risk. However, the effect of necrotizing enterocolitis, feed intolerance, and the number of days to regain birth weight was inconclusive.

Flidel-Rimon (2004) found that infants who did not develop nosocomial sepsis started enteral feeding at a significantly earlier mean age (2.8 days) compared to those who developed NS (4.8 days). However, there was no significant difference in the age at which enteral feeding was started among infants who did or did not develop NEC. Early enteral feeding was associated with a reduced risk of NS but did not change the risk of NEC in VLBW infants. Further research is needed to confirm these results.

Jadcherla et al. (2016) found that implementing a feeding quality improvement program improved neonatal feeding and hospital stay, reducing feeding practices and accelerating oral/enteral feeding variability. Similarly, Vohr et al. (2006, 2007) investigated the effects of ingesting breast milk by extremely low birth weight infants in intensive care units. The study found that breast milk infants had higher mean Bayley Psychomotor Development Index, Bayley Mental Development Index, and Bayley Behavior Rating Scale percentile scores. For each 10 mL/kg/day increase in breast milk, there was a 0.59 points increase in mental developmental index, 0.56 points increase in psychomotor development, 0.99 points increase in total behavior percentile score, and 5% decrease in rehospitalization risk.

1.3 Problem statement

Full-term and preterm neonates admitted to the neonatal intensive care units often require nutritional support. It has been demonstrated that inadequate nutrient intake, notably in the first postnatal week, can be associated with poor growth and other significant clinical consequences in neonates with very low birth rates (Hay, 2018). Because of their prematurity after birth, a considerable percentage of neonates in the intensive care units are unable to tolerate oral and/or enteral feeding immediately. Therefore, neonates often rely on parenteral nutrition for the first few weeks. During this period, partial enteral nutritional support might be provided to meet nutritional needs for adequate growth and maturity. This could also help avoid nutritional deficits in the first period and might help promote adequate growth.

Based on the short preview above, few studies have investigated the effects of early enteral feeding on clinical outcomes of full-term and preterm neonates admitted to intensive care units. Notably, the metabolic pathways in neonates are still immature, and the reservoirs of nutrients are limited. Additionally, the physiologic parameters in

neonates are significantly different from those in older pediatric and adult populations (Chong et al., 2018). Moreover, neonates admitted to the intensive care units are highly vulnerable to malnutrition and poor growth (Hay, 2018; Pineda et al., 2018).

1.4 Study hypothesis

Alternative hypothesis (H1): There is a significant difference in preterm clinical outcomes between neonates who receive early enteral feeding protocol and those who receive standard enteral feeding protocol in neonatal intensive care units in large hospitals in Palestine at the level of P value less than 0.05

Alternative hypothesis (H1): There is a significant difference in weight gain between neonates who receive early enteral feeding protocol and those who receive standard enteral feeding protocol in neonatal intensive care units in large hospitals in Palestine at the level of P value less than 0.05.

Alternative hypothesis (H1): There is a significant difference in the incidence of feeding intolerance between neonates who receive early enteral feeding protocol and those who receive standard enteral feeding protocol in neonatal intensive care units in large hospitals in Palestine at the level of P value less than 0.05.

Alternative hypothesis (H1): Implementing an early enteral feeding protocol for preterm infants in neonatal intensive care units leads to a reduced incidence of infections in preterm infants in the neonatal intensive care unit setting at a significance level of P value less than 0.05.

Alternative hypothesis (H1): Implementing an early enteral feeding protocol for preterm infants in neonatal intensive care units will lead to stable vital signs, including heart rate, respiratory rate, blood pressure, and oxygen saturation, at a significance level of P value less than 0.05

Alternative hypothesis (H1): Implementing an early enteral feeding protocol for preterm infants in neonatal intensive care units leads to improved stability of laboratory values, including BUN, Cr, Na, K, ALBUMIN, Ca, Mg, glucose, and bilirubin levels.

Alternative hypothesis (H1): Implementing an early enteral feeding protocol for preterm infants in neonatal intensive care units leads to higher birth weight and 1st minute APGAR scores within the first 7 days of life in preterm infants in neonatal intensive care units at a significant level of P value less than 0.05.

Alternative hypothesis (H1): Implementing an early enteral feeding protocol for preterm infants in neonatal intensive care units leads to improved blood gas values (PH, PCO₂, PO₂, and HCO₃) in preterm infants in neonatal intensive care units at a significant level of P value less than 0.05.

1.5 Importance of the study

The current work aims to compare nutrition and health outcomes in two hospitals: one that implemented a standardized enteral feeding protocol for very low birth weight preterm infants and another that did not.

1.6 Objectives

- To determine if there is any relationship between early feeding (within 24 to 48 h following neonatal admission to the intensive care unit) for the critical neonate and the clinical outcome.
- To provide evidence- based guidelines for early feeding during critical illness for neonates.

The goals and objectives of a study on the effectiveness of early enteral feeding protocol on preterm clinical outcomes in Neonatal Intensive Care Units (NICUs) would likely be to:

- Determine if the implementation of an early enteral feeding protocol within 24 hours of birth in preterm infants admitted to NICU results in a reduction of NEC incidence compared to standard enteral feeding protocols.
- Evaluate the impact of early enteral feeding on other clinical outcomes, such as weight gain, length of stay in the NICU, and mortality rate.
- Identify any potential risks or adverse effects associated with early enteral feeding.
- Develop evidence- based guidelines for initiating and progressing enteral feedings in preterm infants admitted to NICUs.

- Improve the clinical outcomes of preterm infants admitted to NICUs by providing appropriate nutrition in a timely manner.
- Provide data to assist healthcare providers in making informed decisions about initiating and progressing enteral feedings in preterm infants.

1.7 Definitions

- **Nutritional therapy:** Nutritional therapy is defined as enteral or parental feeding that supplies calories, protein, electrolytes, vitamins, minerals, micronutrients, and fluids to the patient (Specht et al., 2020).
- **Early enteral feeding :** means that preterm or low birth weight infants receive all their nutrition as milk feeds from shortly after birth (within 48 hr) (Nangia et al ., 2018).
- **Enteral nutrition:** Enteral nutrition is defined as the intake of calories, proteins, electrolytic vitamins, minerals, and liquids through the intestine through a functional gastrointestinal tract (Bankhead et al., 2009).
- **Parenteral nutrition:** Parenteral nutrition is defined as the intake of calories, proteins, electrolytes, vitamins, minerals, trace elements, and fluids by other means (such as peripheral parenteral nutrition and total parenteral nutrition). Parenteral nutrition is often used when the gastrointestinal tract is not functional (Worthington et al., 2017).
- **Peripheral parenteral nutrition (PPN):** PPN refers to the administration of a solution of nutrients into veins outside the superior vena cava (Senkal et al., 2021).
- **Total parenteral nutrition (TPN):** TPN refers to the administration of nutrition into the largest vein, such as the superior vena cava, that provides the majority of nutritional needs(Prathik et al., 2021).
- **Bowel necrosis:** Bowel necrosis involves cellular death because of reduced blood flow to the gastrointestinal tract. Bowel necrosis is considered a late stage of different diseases that could be fatal. It can result from inflammation, obstruction, infections, and vascular occlusion(Samuelov et al., 2022).

- **Necrotizing enter colitis:** Necrotizing enter colitis is a frequent disease of the intestinal tract. In this condition, the tissues lining the tract become inflamed, die, and slough off (Maheshwari, 2021).

Chapter Two

Methodology

2.1 Design

Study design: The study was a quasi-experimental study design, in which two groups of preterm infants will be compared: a control group receiving routine care without the early enteral feeding protocol (group C) and an experimental group (group E) receiving early enteral feeding protocol

Intervention: The experimental group received the early enteral feeding protocol involving enteral feedings within 24 hours of birth. The control group received routine care without the early feeding protocol. Both groups received the same formula type, provided through a nasogastric tube.

2.1.1 Data collection

Data was gathered from medical files and direct observation of the infants. The collected data included gestational age, birth weight, gender, Apgar score, length of mechanical ventilation, time to full enteral feedings, hospital stay duration, and adverse events.

Procedures: The procedure for the study is an evaluation of the effectiveness of an early EF model or protocol on preterm clinical outcomes in neonates in NICUs at Government Hospital and private Hospital in Jenin, West Bank-Palestine. The study involved comparing the outcomes of premature neonates who are given an early enteral feeding protocol with those who are not. The study's design and protocol will determine the specific details of the protocol and outcome measurement methods.

The study procedure involves monitoring the vital signs (V/S), such as (HR) heart rate, (BP) blood pressure, (RR) respiratory rate, and (T) temperature. Furthermore, the study procedure involves performing laboratory tests on the premature neonates in the NICUs at Government Hospital and Ibn Sina Hospital in Jenin, Palestine, daily for 7 days or until discharge from the ICU. The tests include HGB (Hemoglobin), WBC (White Blood Cells), PLT (Platelets), Ca (Calcium), Mg (Magnesium), Na (Sodium), K (Potassium), Cr (Creatinine), BUN (Blood Urea Nitrogen), ALBUMINE, Glucose and BILIRUBIN. These test results will be used to evaluate the effectiveness of the early

enteral feeding protocol on preterm clinical outcomes in neonates in NICUs. The specific details of the laboratory test procedures will depend on the study's design and protocol.

The study procedure may also include performing blood gas tests on the premature neonates in the NICUs at Government Hospital and private Hospital in Jenin, Palestine, daily for 7 days or until discharge from the ICU. The blood gas tests include PH (potential of hydrogen), HCO₃ (bicarbonate), PO₂ (partial pressure of oxygen), and PCO₂ (partial pressure of carbon dioxide). These test results will be used to evaluate the acid-base balance and oxygenation status of the premature neonates in the study, which can impact a number of things, such as respiratory distress, metabolic disorders, and the use of mechanical ventilation. The specific details of the blood gas test procedures will depend on the study's design and protocol.

The study procedure may also include monitoring the mechanical ventilator settings and parameters for premature neonates in the NICUs at Government Hospital and private Hospital in Jenin, Palestine, on a daily basis for 7 days or until discharge from the ICU. The data collected may include the mode of ventilation (e.g., CMV, SIMV, etc.), the FiO₂ (fraction of inspired oxygen), the set rate (breaths per minute), the tidal volume (TV), and the PEEP (positive end-expiratory pressure) for each neonate. These settings and parameters will be used to evaluate the effectiveness of the early enteral feeding protocol and monitor the respiratory status of the neonates in the study. The specific details of the mechanical ventilator monitoring will depend on the study's design and protocol.

The study procedure may also include monitoring the feeding and fluid intake, residual volume, and output of the premature neonates in the NICUs at Government Hospital and private Hospital in Jenin, Palestine, on a daily basis for 7 days or until discharge from the ICU. This information is used to evaluate the efficacy of the early EF protocol. The data collected may include the type of feeding (e.g., breast milk, formula, etc). Breast milk is the best option for preterm infants, often with fortifiers added to meet the higher nutritional demands:

- Enteral Feeding: For babies unable to suck or swallow properly, feeding through a tube directly into the stomach may be necessary.

- **Monitoring Growth:** Regular monitoring of growth parameters like weight, length, and head circumference is critical to adjust feeding regimens accordingly. The specific details of the feeding and fluid intake monitoring will depend on the study's design and protocol.

The study procedure may also include monitoring for the presence of complications in premature neonates in the NICUs at Government Hospital and private Hospital in Jenin, Palestine, on a daily basis for 7 days or until discharge from the ICU. The specific complications being monitored will depend on the study's design and protocol, but common complications in premature neonates.

1. Growth Retardation and Poor Weight Gain

- **Failure to Thrive:** Preterm babies often require higher calories, proteins, vitamins, and minerals for proper growth. Improper feeding can result in poor weight gain and growth retardation.
- **Stunted Physical Development:** Poor nutrition can impair skeletal and muscle development.

2. Neurodevelopmental Delays

- **Cognitive Impairment:** Insufficient or improper nutrition during the critical period of brain development can lead to cognitive delays or impairments.
- **Motor Skill Delays:** Deficient intake of essential nutrients can affect the development of fine and gross motor skills.

3. Increased Risk of Infections

- **Weakened Immune System:** Preterm infants have immature immune systems, and poor nutrition can further compromise their ability to fight infections.
- **Sepsis and Necrotizing Enterocolitis (NEC):** Improper feeding, especially overfeeding or inappropriate feeding methods, can lead to NEC, a serious and potentially fatal gastrointestinal condition in preterm infants.

4. Metabolic Issues

- **Electrolyte Imbalances:** Incorrect nutrition can cause imbalances in essential minerals, leading to problems like hypocalcemia (low calcium), hypoglycemia (low blood sugar), or hyponatremia (low sodium).
- **Osteopenia of Prematurity:** Lack of calcium and phosphorus in the diet can lead to weakened bones.

5. Feeding Intolerance

- **Vomiting and Diarrhea:** Preterm infants may experience digestive problems if fed improperly, which can lead to dehydration, electrolyte imbalance, and poor nutrient absorption.
- **Reflux and Aspiration:** Feeding errors, such as overfeeding or improper positioning, can lead to reflux or aspiration, potentially causing respiratory issues or pneumonia.

6. Respiratory Distress

- **Improper feeding, especially overfeeding, can increase the risk of aspiration pneumonia or respiratory distress due to an underdeveloped airway.**

7. Development of Long-Term Conditions

- **Obesity and Metabolic Syndrome:** Inadequate nutrition in the neonatal period can sometimes contribute to the development of obesity, diabetes, and other metabolic conditions later in life due to early nutritional programming.
- **Chronic Health Issues:** Poor nutrition early in life can contribute to long-term issues like cardiovascular disease, diabetes, and high blood pressure.

The monitoring may involve observing the neonates for signs or symptoms of these complications and performing diagnostic tests or procedures to confirm or rule out the presence of complications.

An-Najah National University's institutional review board will approve this study.

A pilot study: A pilot study was conducted before collecting data from respondents on 10% of the total sample. The pilot study included 10 newborns who were divided into two groups, five in each group (5 control, 5 intervention).

Expert Opinion: The document that was prepared previously in order to collect data from the respondents was reviewed by a panel of experts from specialists in scientific research and pediatricians.

2.1.2 Data analysis

Descriptive statistics was used to summarize the data collected. The experimental group will be evaluated against the control group using suitable statistical analyses, including the t-test or chi-square test. A p-value of less than 0.05 will determine statistical significance.

2.2 Study Population

The study population will consist of preterm infants born between 28-37 weeks of gestation who are admitted to the NICU within the first 24 hours of life. Infants who met the inclusion criteria were enrolled in the study. Infants with congenital anomalies or major illnesses that require surgery were excluded.

2.3 Site and setting

The study will be conducted in the neonatal intensive care units (NICUs) of two large hospitals in Jenin: Government Hospital and Private Hospital in Jenin.

2.4 Study period

From January 2023 to December 2023.

2.5 Inclusion criteria

1. Gestational age (GA) between 28week to 37 weeks.
2. Birth weight less than 2500g capable of oral feeding.
3. Preterm intubated neonates or those on mechanical ventilation.

2.6 Exclusion criteria

1. Congenital deficit or anomalies.
2. Neurological deficit or impairment.
3. Infants with nosocomial or congenital sepsis.
4. Requiring surgery.
5. Gestational age more than 37 week or birth weight more than 2500 g.

2.7 Experimental group

The group of preterm infants on mechanical ventilators in the neonate intensive care unit in private Hospital who was receive the early feeding protocol is a subgroup of the experimental group in the study on the effectiveness of EEF protocol on preterm clinical outcomes in NICUs in two large hospitals in Jenin .

This subgroup was consisted of preterm infants who were on mechanical ventilators and admitted to the NICU in private Hospital. These infants was qualified for our research because they met the inclusion criteria for the study, which included being born between 28-37 weeks of gestation, and being admitted to the NICU within the first 24 hrs. of life.

The infants in this subgroup was received enteral feedings within 24 hours of birth as part of the early enteral feeding protocol being studied. The outcomes of this subgroup was compared to the outcomes of the control group to determine the effectiveness of the early enteral feeding protocol, specifically in this subgroup of preterm infants on mechanical ventilator

2.8 Control group (routine care)

A control group in a study is a group of participants who did not received early feeding in Jenin Hospital, where the experimental treatment or intervention was tested. In this case, the control group was the group of participants who received routine care who remains fasting from enteral feeding only. The preterm infant was given intravenous fluids until his vital signs improve completely or after he is removed from the ventilator.

Then, preterm infant is given feeding gradually or in large quantities according to the his improvement.

Table 2.1

Feeding Protocol for preterm infant

Gestational Age	Birth Weight	Clinical Condition	Feeding Tolerance	Enteral Feeding Initiation	Enteral Feeding Progression
<28 weeks	<1000 g	unstable respiratory status, hemodynamic instability, necrotizing enterocolitis	Start with minimal enteral nutrition, increase gradually	1-2 mL/kg every 2-4 hours	Increase by 20-30 mL/kg/day until reaching full enteral feedings
28-32 weeks	1000-1500 g	stable respiratory status, hemodynamic stability, absence of necrotizing enterocolitis	Start with minimal enteral nutrition, increase gradually	10-20 mL/kg every 2-4 hours	Increase by 20-30 mL/kg/day until reaching full enteral feedings

* American Academy of Pediatrics.(2019). Clinical practice guidelines for the provision of nutritional support for preterm infants and guidelines for neonatal resuscitation.Pediatrics, 143(6), e20190293.

The following is a general guideline chart for the initiation and progression of enteral feeding for preterm infants in the NICU:

For infants with a gestational age of less than 28 weeks and a birth weight of less than 1000 grams, who have unstable respiratory status, hemodynamic instability, or necrotizing enterocolitis, minimal enteral nutrition should be initiated and increased gradually by 1-2 mL/kg every 2-4 hours, with an eventual increase of 20-30 mL/kg/day until full enteral feedings are achieved. For those with a gestational age of 28-32 weeks and a birth weight of 1000-1500 grams, who have stable respiratory status, hemodynamic stability, and no necrotizing enterocolitis, minimal enteral nutrition should also be started and increased gradually by 10-20 mL/kg every 2-4 hours, with the same daily increase of 20-30 mL/kg until full enteral feedings are reached. Infants older than 32 weeks with a birth weight greater than 1500 grams, who have stable respiratory status, hemodynamic stability, and no necrotizing enterocolitis, can either start with full enteral feedings or minimal enteral nutrition, increasing gradually by 20-30 mL/kg

every 2-4 hours and then increase by 20-30 mL/kg/day until full enteral feedings are achieved.

Again, this is a general guideline chart and should not be used as a substitute for medical advice from a healthcare provider or a registered dietitian. The feeding plan for preterm infants should be individualized based on the infant's clinical condition and feeding tolerance

2.11 Sample size

The G-power software is used to calculate the required sample size for comparing means and proportions of a specific outcome in two equally sized groups. The formulas that used by the software for sample size calculations take into account the level of statistical significance, the desired power, and the effect size, and this is known as the power analysis. The significance level is the probability of falsely rejecting the null hypothesis even though it is true, the power is the probability of correctly rejecting the null hypothesis if it is false, and the effect size is the difference between the means of the null hypothesis over the standard deviation. The sample size for this study will be determined based on power analysis using the following assumptions: $\alpha=0.05$, $\beta=0.2$, $\text{power}=0.8$, and an effect size of 0.6. Based on the output of the power analysis of the G-power software, the estimated sample size required for this study is 90 infants, with 45 in the experimental group and 45 in the control group.

2.12 Data collection sheet

The researcher has developed a data collection sheet composed of 3 parts;

• Socio-demographic

1. Socio-demographic characteristics of neonates admitted in NICU of Variables
Categories Gestational age in week Birth weight in gram maternal age.

The study may collect data on the sociodemographic features of newborns receiving care in (NICUs) at Government Hospital and IbnSina Hospital in Jenin, Palestine. The variables that may be collected include:

Gestational age in weeks: This refers to the number of weeks a baby has been in the womb at the time of birth. It is used to classify premature neonates.

Birth weight in grams: This refers to the weight of the baby at birth and can be used to classify LBW neonates (Cutland et al., 2017).

Maternal age: This refers to the age of the mother at the time of birth. (Medical Definition of Maternal Age, 2021)

2. The study collected data on the physical characteristics of the neonates admitted to the (NICUs) at Government Hospital and IbnSina Hospital in Jenin, Palestine. The variables that may be collected include:

APGAR score: This is a quick assessment of a newborn's physical condition at the time of birth. It is used to identify newborns in need of immediate medical attention (Simon et al., 2024).

Weight: This refers to the weight of the neonate (Paneth& Thompson, 2018).

APGAR score, weight, are usually measured at the time of birth and then on day 7 or until discharge from the ICU.

These variables can be used to evaluate the physical growth and development of the neonates in the study. The specific measurement techniques and units of measurement will depend on the study's design and protocol.

A conceptual framework is an illustration of the main ideas, connections, and factors that are pertinent to a particular research project. It can guide the study's design and implementation and help interpret and understand the result.

In a study evaluating the efficacy of an early EF on preterm clinical outcomes in neonates in NICUs at Government Hospital and private Hospital in Jenin, Palestine, a conceptual framework may include the following key concepts and relationships:

Independent variable: The early enteral feeding protocol

Dependent variables: Clinical outcomes of preterm neonates, such as growth and development, sepsis, intraventricular hemorrhage, necrotizing enterocolitis (NEC), patent ductusarteriosus, and respiratory distress.

Moderating variables: Elements like gestational age, birth weight, mother age, and the use of mechanical ventilation may have an impact on the relationship between the independent and dependent variables.

Control variables: Variables that could skew the connection between the independent and dependent variables, such as socio- demographic characteristics of the neonates and their families.

The conceptual framework will also include a timeline for measuring different variables such as APGAR score, weight, blood gas, lab test, mechanical ventilator settings, feeding intake, residual volume, output, and complications.

The conceptual framework may be represented visually using a diagram or flowchart, with arrows or lines indicating the relationships between the key concepts and variables.

A flowchart is a type of diagram that can be used to represent a conceptual framework. In a study evaluating the effectiveness of an early EF protocol on preterm clinical outcomes in neonates in NICUs at Government Hospital and IbnSina Hospital in Jenin, Palestine, a flowchart could be used to depict the following steps:

Enrollment of premature neonates in the NICUs at Government Hospital and IbnSina Hospital in Jenin, Palestine.

Administration of early enteral feeding protocol to one group of neonates and standard care to the control group.

Daily monitoring of vital signs, laboratory test results, mechanical ventilator settings, feeding and fluid intake, residual volume, output, and the presence of complications for 7 days or until discharge from the ICU.

Collection of data on socio-demographic characteristics, physical characteristics, and clinical outcomes of the neonates in both groups.

Analysis of the data to determine the efficacy of the early EF protocol on preterm clinical outcomes.

2.13 Statistical analysis

Excel sheet and Version 23 of the Statistical Package for Social Sciences (SPSS) software were used to clean and analyze the data. A descriptive analysis was performed using percentage, frequency, mean, and standard deviation to determine the groups' homogeneity. Comparisons will be made using an independent sample t-test between-group outcomes and a paired sample t-test to investigate pre- and post-tests within each group.

2.14 Ethical consideration

The ethical guidelines provided in the Declaration of Helsinki guided the conduct of this investigation. The scientific research bodies of the two hospitals and the institutional review board (IRB) of An- Najah National University examined and approved the study protocol.

the samples were taken from two hospitals public and private . I am as a researcher obtained approval to conduct this study from the hospital administration and other forms from the university before distributing the questionnaires. Hence, im also got the approval of the head of the department to monitor the children and take the necessary readings, whether they are vital signs or laboratory tests, without intervention. then collected the samples for the study. Equally important, obtained approval from the parents either from the nurse staff who is supervising the case or from me as a researcher. Next, able to collect all the necessary information for the study through the morning shift (shift C) or the evening shift (shift B). In the event that a case was entered among the cases included in the research and the researcher was not present, the researcher was contacted by the team department that was on duty. On the next day, the researcher completes the information that the researcher needs about the child's file. The same procedure was followed in the government hospital in Jenin after obtaining the approval of the nursing supervisor and the head of the department.

Chapter Three

Results

3.1 Introduction

The data analysis in this study was conducted using SPSS Version 23, a statistical tool for social sciences software. The researcher performed descriptive statistics, such as frequencies, percentages, means, and standard deviations, for each variable, indicator, parameter, and measurement examined for the study. The following statistical tests were employed to examine the data and assess the study hypotheses, presuming that a P-value of less than 0.05 indicates significance:

1. The Chi-Square test to test the differences in percentages between the two study groups (C, E) for the qualitative (categorical) variables such as Gender and the Mode types in Mechanical ventilators.
2. The two independent samples T-test to test the differences in means between the two study groups (C, E) for the quantitative variables such as Birth weight, Gestational age, Head circumference, Apgar score, Weight, Height, Total intake, Residual volume, Lab test and Mechanical ventilator indicators, d tests, and Blood gas.

3.2 Study Sample

A study sample included 90 preterm in neonatal intensive care units in two large hospitals in Palestine. The preterms were split into two groups, C and E. Each group contained 45 preterms. Generally, the study sample consisted of 49 males (p=54.4%) and 41 females (p=45.6%). The total mean of the Birth weight of the sample was 1903.97 ± 468.61 grams, and the total mean of the Gestational age was 32.43 ± 2.35 weeks. and the total means of the weights of the preterm are about 1904.39 ± 479.68 grams.

The outcomes of the statistical analyses and comparisons between the research groups (C, E) for the demographic variables are displayed in the following table:

Table 3.1

Comparisons between the study groups for the demographic variables (N=90)

Variable	Group						P-value
	C		E		Total		
	n	Mean ± S.D Or n(%)	n	Mean ± S.D Or n(%)	n	Mean ± S.D Or N(%)	
Gender:							
Male		24(53.3)		25(55.6)		49(54.4)	0.832
Female		21(46.7)		20(44.4)		41(45.6)	
Birth weight	45	2006.8 ± 486.97	45	1801.13 ± 430.59	90	1903.97 ± 468.61	0.037
Gestational age (weeks)	45	32.58 ± 2.43	45	32.29 ± 2.29	90	32.43 ± 2.35	0.563
Apgar score	45	7.69 ± 1.28	45	6.62 ± 1.19	90	7.16 ± 1.34	0.000
Weight	45	2010.76 ± 509.51	45	1798.02 ± 427.41	90	1904.39 ± 479.68	0.035
Total intake	42	119.86 ± 227.25	44	536.11 ± 357.93	86	332.83 ± 365.41	0.000
Residual volume	42	9.45 ± 5.25	44	21.98 ± 11.93	86	15.86 ± 11.18	0.000

*The P-values are related to the two independent samples T-test for the quantitative variables and the Chi-square test for the qualitative or categorical variables; the numbers in the table represent (Mean ± Standard deviation) or N(%).

The aforementioned table's results indicate that only the following variables—birth weight, Apgar score1, weight, total intake, and residual volume—show significant differences between the study groups (C,E) at the 0.05 level.

In terms of birth weight, the data indicate that group C's mean (2006.8) is substantially greater than group E's (1801.13); the test's P-value is 0.037. With respect to the Apgar score, the findings indicate that group C's mean (mean = 7.69) is considerably greater than group E's mean (mean = 6.62); the test's P-value is 0.000.

With respect to weight, the findings indicate that group C's mean (2010.76) is much greater than group E's mean (1798.02); the test's P-value is 0.035.

The results indicate that, with regard to total intake, group C's mean (mean = 119.86) is considerably lower than group E's mean (mean = 536.11); the test's P-value is 0.000.

In conclusion, with respect to residual volume, the data indicates that group C's mean (mean = 9.45) is considerably lower than group E's mean (mean = 21.98), with a test P-value of 0.000.

Figure 3.1

Comparisons between the study groups for the Total Intake .

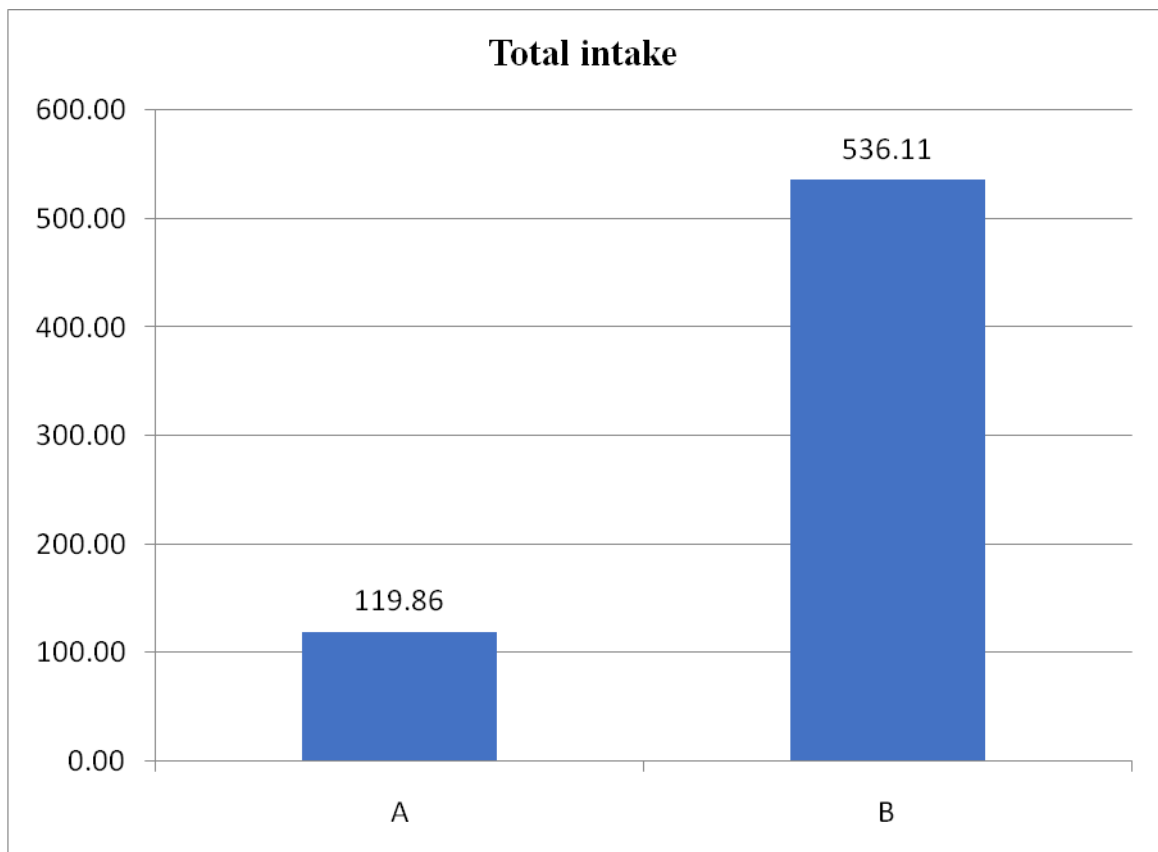
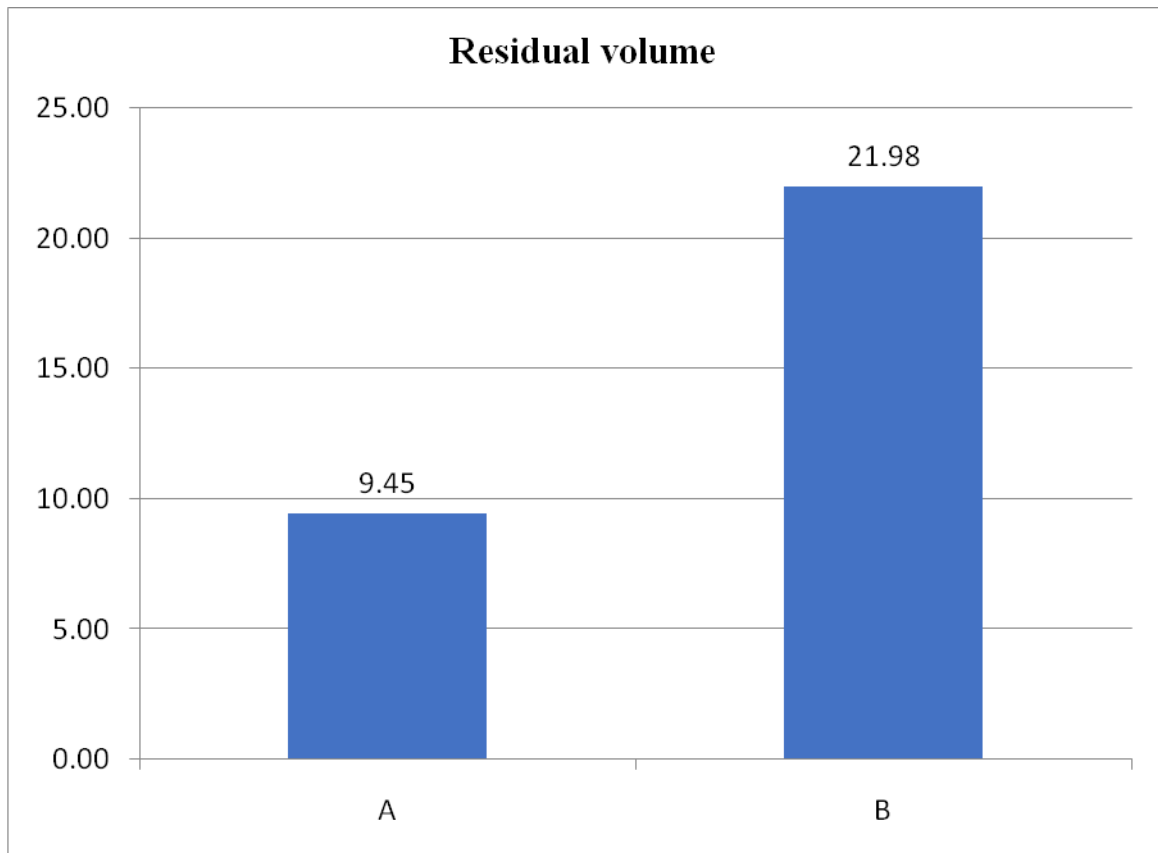


Figure 3.2

Comparisons between the study groups for the Residual volume



TableD.1 in appendix d : Comparisons between the study groups for the SBP variable (N=90).*illustrates the findings of the statistical testing and comparisons between the study groups (C,E) for the SBP.

The results in the following table demonstrate that, with the exception of days 6 and 7, there are significant differences in SBP and Total SBP at the 0.05 level between the study groups (C,E). The findings demonstrate that all SBP values in group C during these days (days 1 through 5) are much lower than the comparable levels in group E.

Day 1 results indicate that group C's mean SBP (mean = 66.11) is considerably lower than group E's mean (mean = 71.22); the test's P-value is 0.012.

Day 2 results indicate that group C's mean SBP (mean = 67.2) is considerably lower than group E's mean (mean = 74.78); the test's P-value is 0.000.

Day 3 data indicate that group C's mean SBP (mean = 69.45) is significantly lower than group E's mean SBP (mean = 74.07); the test's P-value is 0.028.

Day 4 results indicate that group C's mean SBP (mean = 70.8) is considerably lower than group E's mean (mean = 76.2); the test's P-value is 0.023.

Day 5 data indicate that group C's mean SBP (mean = 72.05) is significantly lower than group E's mean SBP (mean = 77.98); the test's P-value is 0.004.

In terms of overall SBP, the findings indicate that group C's mean (Mean=71.09) is substantially lower than group B's mean (Mean=75.35); the test's P-value is 0.003.

The next table presents the findings of the statistical testing and comparisons between the study groups (C, E) for the DEP:

Table D.2 in appendix D: Comparisons between the study groups for the DBP variable (N=90). *indicates that only the first three days of DBP showed significant differences (at the 0.05 level) between the research groups (C, E). The findings indicate that group C's DBP levels on these days are noticeably lower than group E's equivalent levels.

Day 1 results indicate that group C's DBP mean (mean = 36.73) is significantly lower than group E's mean (mean = 41.02); the test's P-value is 0.022.

Day 2 results indicate that group C's DBP mean (mean = 40.07) is significantly lower than group E's mean (mean = 44); the test's P-value is 0.022.

Day 3 data indicate that group C's DBP mean (mean = 39.83) is substantially lower than group E's mean (mean = 43.2); the test's P-value is 0.040.

The next table shows the findings of the statistical testing and comparisons between the study groups (C, E) for the HR:

Table3.2*Comparisons between the study groups for the HR variable (N=90).**

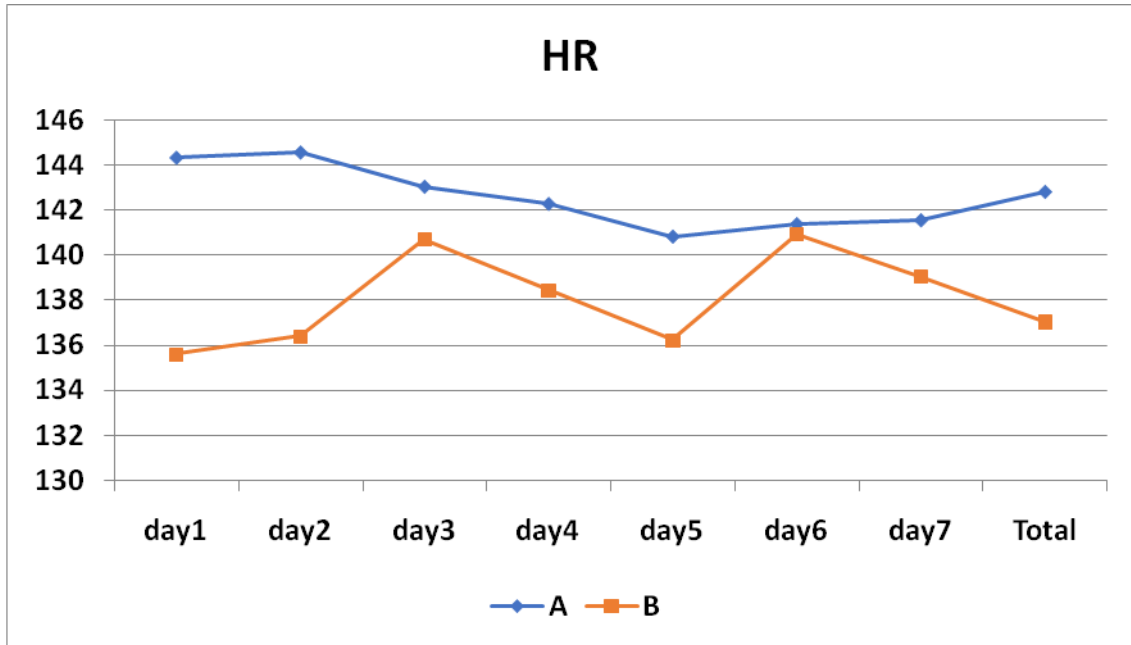
Variable : HR	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	144.31 ± 18.93	45	135.6 ± 16.81	90	139.96 ± 18.33	0.023
day2	44	144.55 ± 12.74	45	136.38 ± 16.83	89	140.42 ± 15.42	0.012
day3	43	143.02 ± 14.52	44	140.68 ± 13.37	87	141.84 ± 13.92	0.436
day4	42	142.26 ± 12.25	44	138.43 ± 13.81	86	140.3 ± 13.14	0.036
day5	42	140.81 ± 12	44	136.2 ± 11.99	86	138.45 ± 12.14	0.033
day6	41	141.37 ± 8.88	43	140.91 ± 12.75	84	141.13 ± 10.97	0.849
day7	41	141.54 ± 12.37	43	139.05 ± 13.36	84	140.26 ± 12.87	0.379
Total	45	142.8 ± 9.76	45	137.03 ± 13.83	90	139.92 ± 12.25	0.025

*The P-values are related to the two independent samples T-test for the quantitative variables; the numbers in the table represent (Mean ± Standard deviation).

The table showed significant differences at the 0.05 level between the study groups (C and E) in heart rate (HR) on days 1, 2, 4, and 5, as well as in the total HR. The results indicate that the HR levels on these days in group C are significantly higher than the corresponding levels in group E. On day 1, group C's mean HR (144.31) was substantially higher than group E's (135.6), with a test P-value of 0.023. On day 2, group C's mean HR (144.55) was significantly higher than group E's (136.38), with a P-value of 0.012. On day 4, group C's mean HR (142.26) was notably higher than group E's (138.43), with a P-value of 0.036. On day 5, group C's mean HR (140.81) was significantly higher than group E's (136.2), with a P-value of 0.033. Overall, the findings indicate that group C's mean HR (142.8) was much higher than group E's mean HR (137.03), with a test P-value of 0.025.

Figure 3.3

Comparisons between the study groups for the heart rate variable .



Results in the next table illustrate the statistical testing and comparisons between the study groups (C, E) for the TEMP:

Table D.3 in appendix D: Comparisons between the study groups for the TEMP variable (N=90).* The findings in the previous table indicate that the p-values for the test are more than 0.05 and that there are no significant differences at the 0.05 level in TEMP for any day between the study groups (C, E).

The outcomes of the statistical tests are displayed in the table below, which shows the comparisons between the study groups (C, E) for the RR:

Table D.4 in appendix D: Comparisons between the study groups for the RR variable (N=90).* shows no significant differences at 0.05 level between the study groups (C, E) in RR in all days. The p-values of the test are higher than 0.05.

The next table presents the findings of the statistical testing and comparisons between the study groups (C, E) for the HGB:

Table D.5 in appendix D: Comparisons between the study groups for the HGB variable (N=90).* revealed that at 0.05 level, there are no significant differences between the study groups (C, E) in HGB in all days. The p-values of the test are higher than 0.05.

In the next table, we show the findings about the statistical testing and comparisons between the study groups (C, E) for the PLT:

Table D.6 in appendix D: Comparisons between the study groups for the PLT variable (N=90).*. According to the table, which shows the results regarding the PLT variable at the 0.05 significance level, there are significant differences between the study groups (C and E) in PLT on all days and in the total PLT. The results show that the PLT levels in group C are significantly lower on these days than the corresponding levels in group E. On day 1, group C's mean PLT (209.68) was significantly lower than group E's mean PLT (249.38), with a test P-value of 0.017. On day 2, group C's mean PLT (214.31) was substantially lower than group E's mean PLT (243.22), with a P-value of 0.011. On day 3, group C's mean PLT (209.68) was substantially lower than group E's mean PLT (271.2), with a test P-value of 0.000. On day 4, group C's mean PLT (212.38) was considerably lower than group E's mean PLT (260.14), with a P-value of 0.012. On day 5, group C's mean PLT (215.25) was considerably lower than group E's mean PLT (275.55), with a P-value of 0.000. On day 6, data indicate that group C's PLT in mean (202.58) is considerably lower than group E's mean (292.21), with a test P-value of 0.000. On day 7, data indicate that group C's PLT mean (199.67) is considerably lower than group E's mean (286.64), with a test P-value of 0.000.

The P-value of the test is 0.000. With regard to the total PLT, the results indicate that the mean PLT in group C (Mean=217.16) is significantly lower than that in group E (Mean=265).

In the next table, a finding for statistical testing and comparisons between the study groups (C, E) for the BUN:

Table D.7 in appendix D: Comparisons between the study groups for the BUN variable (N=90).*Table D.7 shows significant differences at the 0.05 level between the study groups (C and E) in BUN on days 1, 4, 6, and 7 and in the total BUN. The results show that the BUN levels on these days in group C are significantly higher than the corresponding levels in group E. Day 1 results indicate that group C's mean BUN (19.02) is substantially greater than group E's (15.29), with a test P-value of 0.027. Day 4 results indicate that group C's mean BUN (23.91) is substantially greater than group E's (15.43), with a test P-value of 0.004. Day 6 data indicate that group C's mean BUN

(21.8) is substantially higher than group E's mean BUN (16.15), with a test P-value of 0.008. Day 7 data indicate that group C's mean BUN (20.5) is substantially higher than group E's (13.9), with a test P-value of 0.008. In terms of total BUN, the data indicate that group C's mean BUN (19.15) is much higher than group E's mean BUN (15.94), with a test P-value of 0.040.

The next table presents the findings of the statistical testing and comparisons between the study groups (C, E) for the Cr:

Table D.8 in appendix D: Comparisons between the study groups for the Cr variable (N=90). *reveals no significant differences at 0.05 level between the study groups (C, E) in Cr in all days and in the Total Cr, the p-values of the test are higher than 0.05.

The following table presents the findings of the statistical testing and comparisons between the study groups (C, E) for the Na:

Table D.9 in appendix D: Comparisons between the study groups for the Na variable (N=90). *revealed significant differences at 0.05 level between the study groups (C, E) in Na only on day 2 and day 6. The results show that the Na levels in group C during these two days are significantly higher than the corresponding levels in group E.

Day 2 data indicate that group C's mean (138.93) is substantially higher than group E's mean (136.25), with a P-value of 0.046 for the test.

Day 6 data indicate that group C's mean (140) is substantially higher than group E's mean (137), with a test P-value of 0.030.

The next table illustrates the findings of the statistical testing and comparisons between the study groups (C, E) for the K variable:

Table D.10 in appendix D: Comparisons between the study groups for the K variable (N=90). The results in the above table demonstrate that there are significant differences ($P < 0.05$) between the study groups (C, E) in K only on day 2 and in Total K. Specifically, on day 2, group C's mean (Mean = 4.87) is significantly higher than group E's mean (Mean = 4.43), and the test's P-value is 0.011. Furthermore, the results indicate that with respect to total K, group C's mean (Mean=4.76) is much higher than group E's mean (Mean=4.36); the test's P-value is 0.021.

In the table, we illustrate the findings of the statistical testing and comparisons between the study groups (C, E) for the ALBUMINE variable:

Table D.11 in appendix D: Comparisons between the study groups for the ALBUMINE variable (N=90).*According to the results in Table D.11, there are significant differences at 0.05 level between the study groups (C, E) in ALBUMINE only on day5 and in the total ALBUMINE.

Day 5 data indicate that group C's mean (Mean=2.8) is substantially higher than group E's mean (Mean=1.5), with a test P-value of 0.008. Furthermore, with respect to the overall ALBUMINE, the findings indicate that group C's mean (mean = 8.88) is much greater than group E's mean (mean = 2.34), with a P-value of 0.040 for the test.

The next table presents the findings of the statistical testing and comparisons between the study groups (C, E) for the WBC variable:

Table3.3

*Comparisons between the study groups for the WBC variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
WBC	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	14.85 ± 4.64	45	12.34 ± 4.37	90	13.59 ± 4.66	0.010
day2	31	15.25 ± 4.72	45	12.84 ± 4.05	76	13.82 ± 4.47	0.020
day3	36	13.5 ± 4.39	44	11.87 ± 3.77	80	12.6 ± 4.12	0.079
day4	24	15.28 ± 3.23	44	11.43 ± 3.44	68	12.79 ± 3.82	0.000
day5	29	15.16 ± 4.99	44	11.75 ± 3.86	73	13.11 ± 4.62	0.002
day6	28	13.54 ± 4.31	43	12.06 ± 4.95	71	12.64 ± 4.73	0.049
day7	29	12.17 ± 3.86	42	12.23 ± 4.72	71	12.21 ± 4.36	0.950
Total	45	13.72 ± 3.92	45	12.13 ± 3.47	90	12.92 ± 3.77	0.045

*The P-values are related to the two independent samples T-test for the quantitative variables; the numbers in the table represent (Mean ± Standard deviation).

According to the findings presented in Table 3.14, at 0.05 level, there are significant differences between the study groups (C, E) in WBC in day1, day2, day4, day5, day6, and in the Total WBC. The results show that the WBC levels in group C on all these days are significantly higher than the corresponding levels in group E.

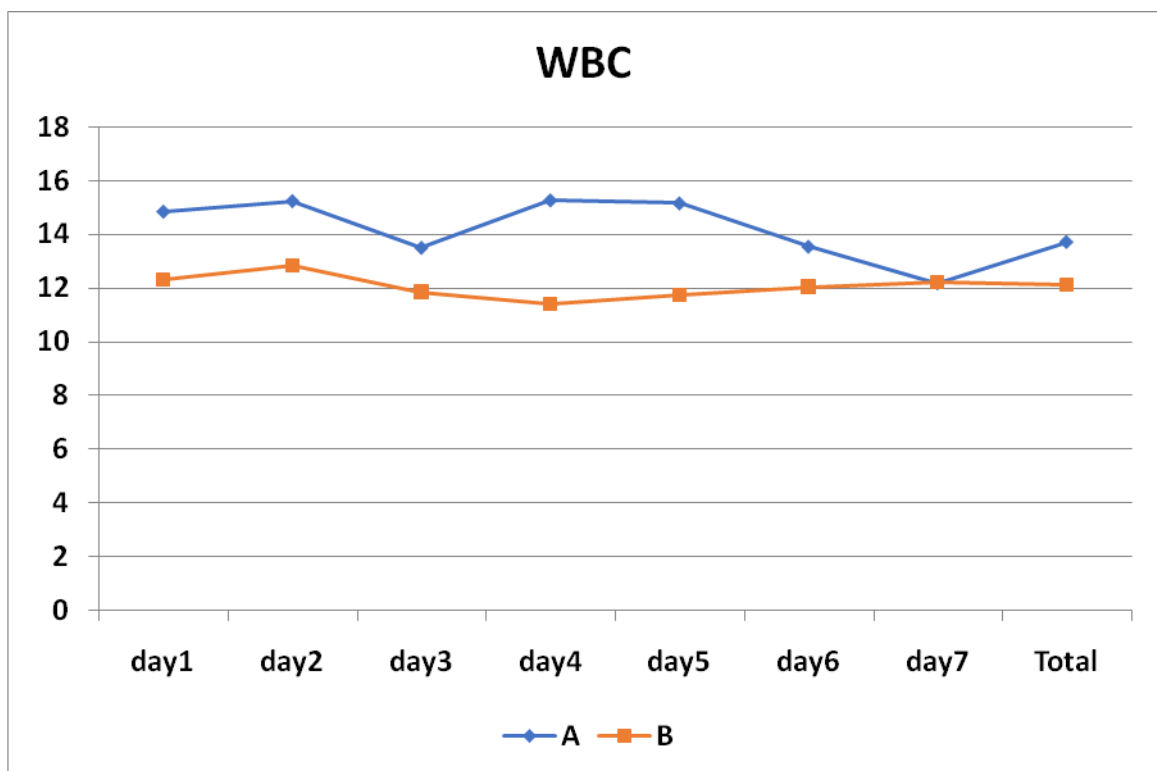
Day 1 data indicate that group C's WBC mean (mean = 14.85) is substantially higher than group E's mean (mean = 12.34); the test's P-value is 0.010.

Day 2 data indicate that group C's WBC mean (mean = 15.25) is substantially higher than group E's mean (mean = 12.84); the test's P-value is 0.020. Day 4 data indicate that group C's WBC mean (mean = 15.28) is substantially higher than group E's mean (mean = 11.43), with a test P-value of 0.000.

Day 5 data indicate that group C's WBC mean (mean = 15.16) is substantially higher than group E's mean (mean = 11.75), with a test P-value of 0.002. Day 6 data indicate that group C's WBC mean (mean = 13.54) is substantially higher than group E's mean (mean = 12.06), with a test P-value of 0.049. In terms of total WBC, the data indicate that group C's mean (mean = 13.72) is considerably greater than group E's mean (mean = 12.13); the test's P-value is 0.045.

Figure 3.4

Comparisons between the study groups for the white blood cell variable.



The next table presents the findings of the statistical testing and comparisons between the study groups (C, E) for the Ca variable:

Table D.12 in appendix D: Comparisons between the study groups for the Ca variable (N=90).*The results in the above table demonstrate that there are significant differences in CA only on day 1, day 7, and in the Total CA between the research groups (C, E) at the 0.05 level. The findings indicate that group C's CA levels on these particular days are noticeably lower than group E's equivalent levels.

Day 1 results indicate that group C's mean (mean = 6.03) is considerably lower than group E's mean (mean = 6.82); the test's P-value is 0.028.

Day 7 data indicate that group C's mean (mean = 6.84) is considerably lower than group E's mean (mean = 8.21); the test's P-value is 0.007.

In terms of the overall CA, the findings indicate that group C's mean (mean=6.66) is considerably lower than group E's mean (mean=7.58); the test's P-value is 0.018.

The next table (3.16) demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the Glucose variable:

Table D.13 in appendix D: Comparisons between the study groups for the Glucose variable (N=90).*The finding in the previous table (D.13) above found that there are no significant differences at 0.05 level between the study groups (C, E) in Glucose in all days. The p-values of the test are higher than 0.05.

The next table demonstrates the results of the statistical testing and comparisons between the study groups (C, E) for the BILIRUBIN variable:

Table D.14 in appendix D: Comparisons between the study groups for the BILIRUBIN variable (N=90).*In the previous table (D.14), the findings revealed that there are significant differences at 0.05 levels between the study groups (C and E) in BILIRUBIN in all days and in the total BILIRUBIN. The results show that the BILIRUBIN levels in group C are significantly higher these days than the corresponding levels in group E.

Day 1 data indicate that group C's BILIRUBIN mean (mean = 10.79) is substantially greater than group E's mean (mean = 7.16), with a 0.000 P-value for the test.

Day 2 data indicate that group C's BILIRUBIN mean (mean = 11.25) is substantially greater than group E's mean (mean = 6.82), with a test P-value of 0.000. Day 3 data indicate that group C's BILIRUBIN mean (mean = 10.57) is substantially greater than group E's mean (mean = 7.2), with a test P-value of 0.008. Day 4 data indicate that group C's BILIRUBIN mean (mean = 11.36) is substantially greater than group E's mean (mean = 7.47), with a test P-value of 0.001.

Day 5 results indicate that group C's BILIRUBIN mean (mean = 10.82) is substantially higher than group E's mean (mean = 7.53); the test's P-value is 0.001. Day 6 data indicate that group C's BILIRUBIN mean (mean = 10.25) is substantially higher than group E's mean (mean = 6.57), with a test P-value of 0.001. Day 7 data indicate that group C's BILIRUBIN mean (mean = 10) is substantially higher than group E's mean (mean = 6.59); the test's P-value is 0.003.

Regarding the total BILIRUBIN, the findings indicate that the mean of BILIRUBIN in group C (Mean=9.32) is significantly higher than that of group E (Mean=7.05), and the P-value of the test is 0.005.

The next table (3.18) demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the PH variable:

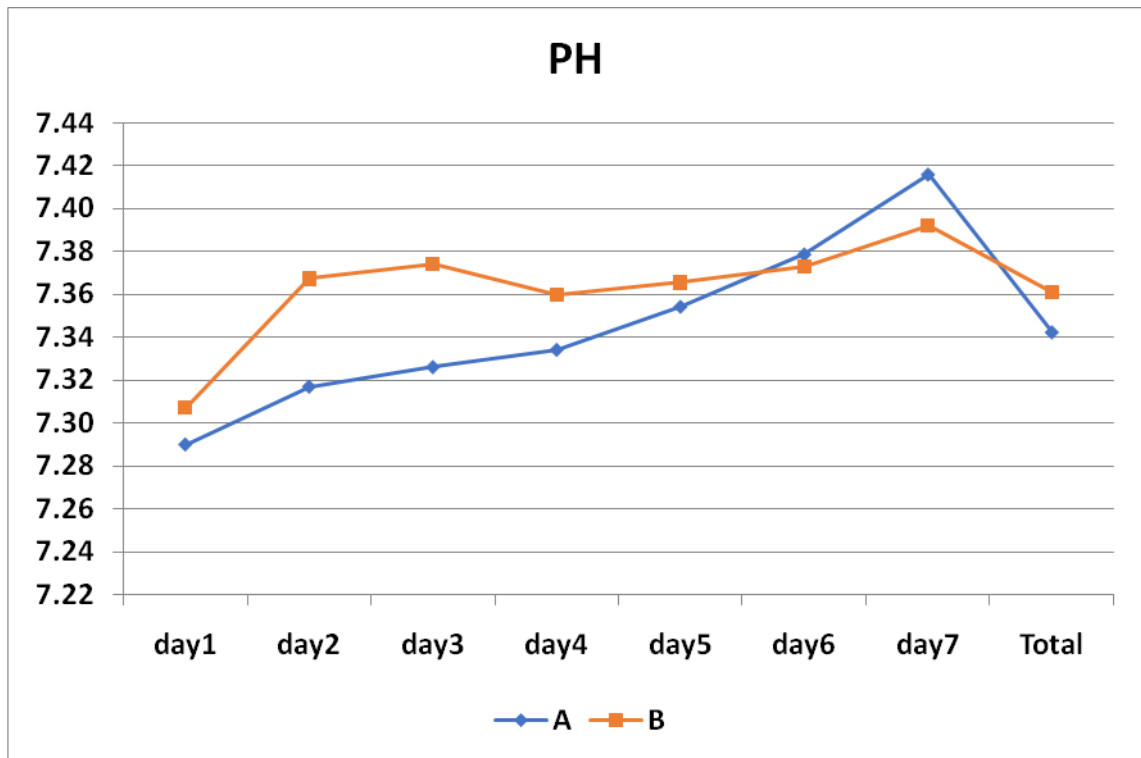
Table D.15 in appendix D: Comparisons between the study groups for the PH variable (N=90). *Table (D.15) findings indicate that there are significant differences at 0.05 level between the study groups (C, E) in PH only on day2 and day3. The results show that the PH levels in group C are significantly lower these days than in group E.

On day2, the results show that the mean of PH in group C (Mean=7.32) is significantly lower than that in group E (Mean=7.37). The P-value of the test is 0.010.

On day3, the findings found that the mean of PH in group C (Mean=7.33) was significantly lower than that in group E (Mean=7.37). The P-value of the test is 0.004.

Figure 3.5

Comparisons between the study groups for the PH variable

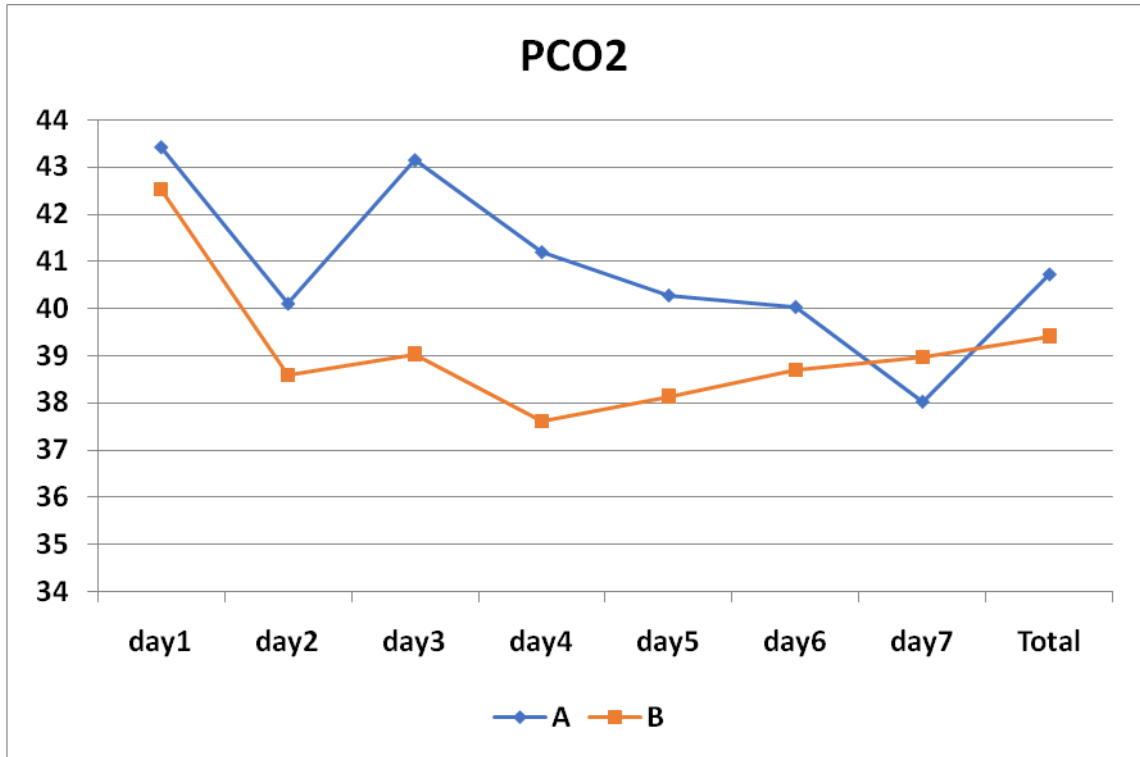


The next table (D.16 in appendix D) demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the PCO₂ variable:

Table D.16 in appendix D: Comparisons between the study groups for the PCO₂ variable (N=90).*The findings in the (D.16) table demonstrate that there are significant differences at 0.05 level between the study groups (C, E) in PCO₂ only on day4. The results show that the mean of PCO₂ in group C (Mean=41.19) is significantly higher than that in group E (Mean=37.61). The P-value of the test is 0.032.

Figure 3.6

Comparisons between the study groups for the pco2 variable .



The next table (D.17 in appendix D) demonstrates the results of the statistical testing and comparisons between the study groups (C, E) for the PO₂ variable:

Table D.17 in appendix D: Comparisons between the study groups for the PO₂ variable (N=90). *In Table (Table D.17 in appendix D) the results indicate that there are significant differences at 0.05 level between the study groups (C, E) in PO₂ only on day 3; the results show that the mean of PO₂ in group C (Mean=84.63) is significantly higher than that in group E (Mean=75.63), the P-value of the test is 0.035.

The next table D.18 in appendix D) demonstrates the results of the statistical testing and comparisons between the study groups (C, E) for the HCO₃ variable:

Table D.18 in appendix D: Comparisons between the study groups for the HCO₃ variable (N=90). *The findings in the previous table (Table D.18 in appendix D) indicate that there are significant differences at 0.05 level between the study groups (C, E) in HCO₃ in all days and in the Total HCO₃ except in day 5. The results show that the

HCO₃ levels in group C are significantly lower these days than the corresponding levels in group E.

On day1, the findings indicate that the mean of HCO₃ in group C (Mean=18.66) is significantly lower than that in group E (Mean=21.22). The P-value of the test is 0.038.

On day2, the findings found that the mean of HCO₃ in group C (Mean=18.33) is significantly lower than that in group E (Mean=21.24). The P-value of the test is 0.010.

On day3, the findings revealed that the mean of HCO₃ in group C (Mean=18.8) is significantly lower than that in group E (Mean=22.01). The P-value of the test is 0.001.

On day4, the findings demonstrate that the mean of HCO₃ in group C (Mean=18.82) is significantly lower than that in group E (Mean=22.1). The P-value of the test is 0.001.

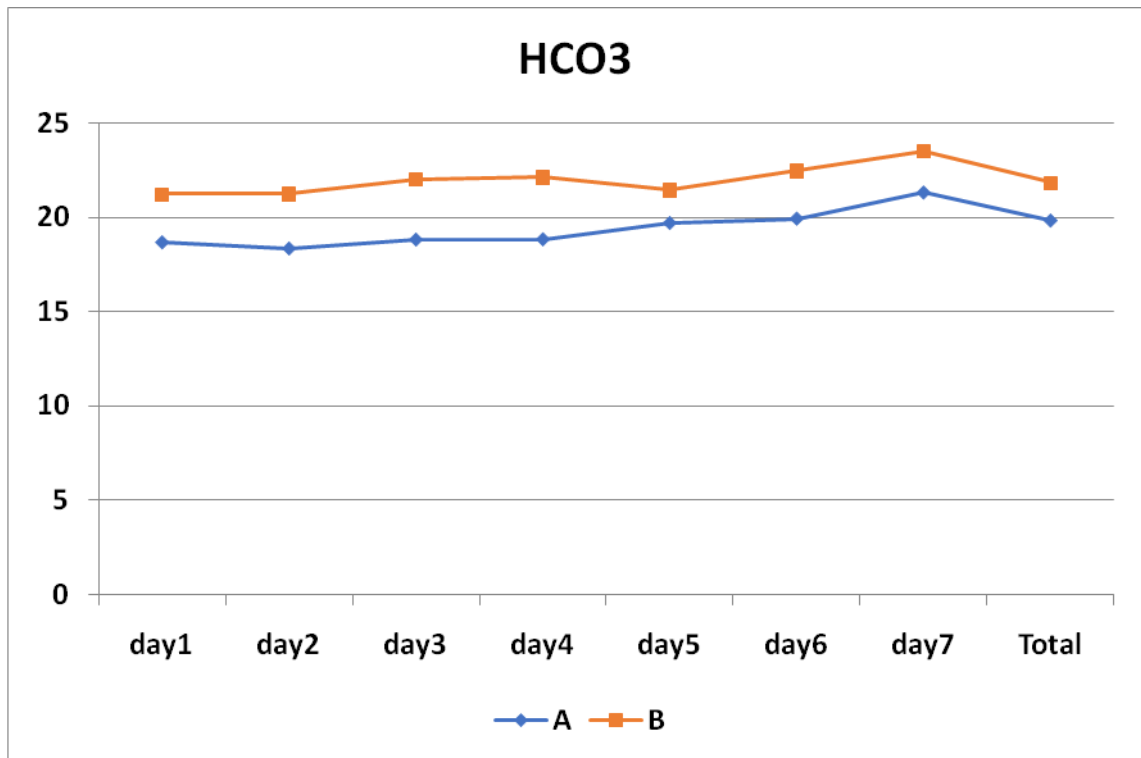
On day6, the findings revealed that the mean of HCO₃ in group C (Mean=19.92) is significantly lower than that in group E (Mean=22.45). The P-value of the test is 0.003.

On day7, the findings found that the mean of HCO₃ in group C (Mean=21.31) is significantly lower than that in group E (Mean=23.48). The P-value of the test is 0.021.

Regarding the total HCO₃, the findings indicate that the mean of HCO₃ in group C (Mean=19.82) is significantly lower than that in group E (Mean=21.82). The P-value of the test is 0.012.

Figure 3.7

Comparisons between the study groups for the HCO₃ variable.



The next table (3.4) illustrates the findings of the statistical testing and comparisons between the study groups (C, E) for the Nasal CPAP mode type:

Table 3.4*Comparisons between the study groups for the Nasal cpap mode type (N=90). **

Mode type:		Group		Total	P-value
Nasal cpap		C	E		
Shift	Day	N(%)	N(%)	N(%)	
A	day1	7(15.6)	4(8.9)	11(12.2)	0.334
A	day2	7(21.2)	6(15)	13(17.8)	0.764
A	day3	3(8.8)	7(17.9)	10(13.7)	0.180
A	day4	9(27.3)	5(16.7)	14(22.2)	0.245
A	day5	11(33.3)	3(12)	14(24.1)	0.020
A	day6	10(35.7)	3(17.6)	13(28.9)	0.036
A	day7	7(25.9)	2(14.3)	9(22)	0.079
B	day1	6(15.4)	4(9.3)	10(12.2)	0.502
B	day2	6(18.8)	6(15)	12(16.7)	0.999
B	day3	3(9.1)	7(17.9)	10(13.9)	0.180
B	day4	9(28.1)	5(16.7)	14(22.6)	0.245
B	day5	11(34.4)	3(12.5)	14(25)	0.020
B	day6	10(37)	3(18.8)	13(30.2)	0.036
B	day7	7(29.2)	2(14.3)	9(23.7)	0.079
C	day1	6(14.6)	4(8.9)	10(11.6)	0.502
C	day2	6(18.8)	6(15)	12(16.7)	0.999
C	day3	5(15.2)	7(17.9)	12(16.7)	0.535
C	day4	9(28.1)	5(17.9)	14(23.3)	0.245
C	day5	11(34.4)	3(12.5)	14(25)	0.020
C	day6	10(37)	3(18.8)	13(30.2)	0.036
C	day7	7(29.2)	2(14.3)	9(23.7)	0.079

The findings in the previous table (3.4) indicate that Nasal cpap percentages increase by days in group (C) only in all shifts, and the findings that there are significant differences at 0.05 level between the study groups (C, E) in Nasal cpap mode type shift-A only in day5 and day6. The findings indicate that the percentage of (Nasal cpap) in group E on the day (n=3, p=12%) is significantly lower than that in group C (n=11, p=33.3%), and the P-value of the test is 0.020. Also, the percentage of (Nasal cpap) in group E on day6 (n=3, p=17.6%) is significantly lower than that in group C (n=10, p=35.7%). The P-value of the test is 0.036. The same results appeared in shift B and shift C.

The next table (3.5) shows the findings of the statistical testing and comparisons between the study groups (C, E) for the SIMV mode type:

Table 3.5

*Comparisons between the study groups for the SIMV mode type (N=90).**

Mode type:		Group		Total	P-value
SIMV		C	E		
Shift	Day	N(%)	N(%)	N(%)	
A	day1	26(57.8)	34(75.6)	60(66.7)	0.074
A	day2	24(72.7)	31(77.5)	55(75.3)	0.130
A	day3	24(70.6)	21(53.8)	45(61.6)	0.527
A	day4	16(48.5)	17(56.7)	33(52.4)	0.827
A	day5	11(33.3)	11(44)	22(37.9)	0.999
A	day6	8(28.6)	5(29.4)	13(28.9)	0.368
A	day7	9(33.3)	1(7.1)	10(24.4)	0.007
B	day1	26(66.7)	34(79.1)	60(73.2)	0.074
B	day2	24(75)	31(77.5)	55(76.4)	0.130
B	day3	24(72.7)	21(53.8)	45(62.5)	0.527
B	day4	16(50)	17(56.7)	33(53.2)	0.827
B	day5	11(34.4)	11(45.8)	22(39.3)	0.999
B	day6	8(29.6)	5(31.3)	13(30.2)	0.368
B	day7	9(37.5)	1(7.1)	10(26.3)	0.007
C	day1	26(63.4)	34(75.6)	60(69.8)	0.074
C	day2	24(75)	31(77.5)	55(76.4)	0.130
C	day3	22(66.7)	21(53.8)	43(59.7)	0.833
C	day4	16(50)	17(60.7)	33(55)	0.827
C	day5	11(34.4)	11(45.8)	22(39.3)	0.999
C	day6	8(29.6)	5(31.3)	13(30.2)	0.368
C	day7	9(37.5)	1(7.1)	10(26.3)	0.007

The findings in the previous table (3.5) indicate that SIMV percentages decrease by days in group (C) and group (E) in all shifts, and the results show that there are significant differences at 0.05 level between the study groups (C, E) in SIMV mode type shift-A only in day7. The findings indicate that the percentage of (SIMV) in group E on day7 (n=1, p=7.1%) is significantly lower than that in group C (n=9, p=33.3%). The P-value of the test is 0.007. The same results appeared in shiftB and shiftC.

The next table (3.6) demonstrates the results of the statistical testing and comparisons between the study groups (C, E) for the O2 Free Flow mode type:

Table 3.6

*Comparisons between the study groups for the O2 Free Flow mode type (N=90).**

Mode type:		Group		Total	P-value
O2 Free Flow		C	E	N(%)	
Shift	Day	N(%)	N(%)	N(%)	
A	day1	0(0)	0(0)	0(0)	-----
A	day2	0(0)	0(0)	0(0)	-----
A	day3	0(0)	2(5.1)	2(2.7)	0.153
A	day4	1(3)	4(13.3)	5(7.9)	0.167
A	day5	0(0)	6(24)	6(10.3)	0.011
A	day6	1(3.6)	3(17.6)	4(8.9)	0.306
A	day7	0(0)	3(21.4)	3(7.3)	0.039
B	day1	0(0)	0(0)	0(0)	-----
B	day2	0(0)	0(0)	0(0)	-----
B	day3	0(0)	2(5.1)	2(2.8)	0.153
B	day4	1(3.1)	4(13.3)	5(8.1)	0.167
B	day5	0(0)	6(25)	6(10.7)	0.011
B	day6	1(3.7)	3(18.8)	4(9.3)	0.306
B	day7	0(0)	3(21.4)	3(7.9)	0.039
C	day1	0(0)	0(0)	0(0)	-----
C	day2	0(0)	0(0)	0(0)	-----
C	day3	0(0)	2(5.1)	2(2.8)	0.153
C	day4	1(3.1)	4(14.3)	5(8.3)	0.167
C	day5	0(0)	6(25)	6(10.7)	0.011
C	day6	1(3.7)	3(18.8)	4(9.3)	0.306
C	day7	0(0)	3(21.4)	3(7.9)	0.039

The findings in the (3.6) table indicate that O2 Free Flow percentages increase slightly by days in group (C) while increasing at a higher rate in group (E) in all shifts. The findings indicate that there are significant differences at 0.05 level between the study groups (C, E) in O2 Free Flow mode type shift-A only on day5 and day7. The findings also show that the percentage of (O2 Free Flow) in group E on day5 (n=6, p=24%) is significantly higher than that in group C (n=0, p=0%). The P-value of the test is 0.011. The results also show that the percentage of (O2 Free Flow) in group E in day7 (n=3, p=21.4%) is significantly higher than that in group C (n=0, p=0%). The P-value of the test is 0.039. The same results appeared in shift E and shift C.

The next table (3.7) illustrates the findings of the statistical testing and comparisons between the study groups (C, E) for the O2 room air mode type:

Table 3.7

*Comparisons between the study groups for the O2 room air mode type (N=90).**

Mode type:		Group		Total	P-value
O2 room air		C	E	N(%)	
Shift	Day	N(%)	N(%)	N(%)	
A	day1	0(0)	0(0)	0(0)	-----
A	day2	0(0)	0(0)	0(0)	-----
A	day3	1(2.9)	3(7.7)	4(5.5)	0.306
A	day4	0(0)	0(0)	0(0)	-----
A	day5	1(3)	0(0)	1(1.7)	0.315
A	day6	3(10.7)	2(11.8)	5(11.1)	0.645
A	day7	2(7.4)	4(28.6)	6(14.6)	0.398
B	day1	0(0)	0(0)	0(0)	-----
B	day2	0(0)	0(0)	0(0)	-----
B	day3	1(3)	3(7.7)	4(5.6)	0.306
B	day4	0(0)	0(0)	0(0)	-----
B	day5	1(3.1)	0(0)	1(1.8)	0.315
B	day6	2(7.4)	2(12.5)	4(9.3)	0.999
B	day7	1(4.2)	4(28.6)	5(13.2)	0.167
C	day1	0(0)	0(0)	0(0)	-----
C	day2	0(0)	0(0)	0(0)	-----
C	day3	1(3)	3(7.7)	4(5.6)	0.306
C	day4	0(0)	0(0)	0(0)	-----
C	day5	1(3.1)	0(0)	1(1.8)	0.315
C	day6	2(7.4)	2(12.5)	4(9.3)	0.999
C	day7	1(4.2)	4(28.6)	5(13.2)	0.167

The results in the previous table (3.7) indicate that O2 room air percentages increase by days in group (C) and group (E) in all shifts, and the findings refer. There are no significant differences at 0.05 level between the study groups (C, E) in O2 room air mode type on all days and shifts.

The following table (D.19 in appendix D) demonstrates the results of the statistical testing and comparisons between the study groups (C, E) for the total Fio2 variables of all Shifts:

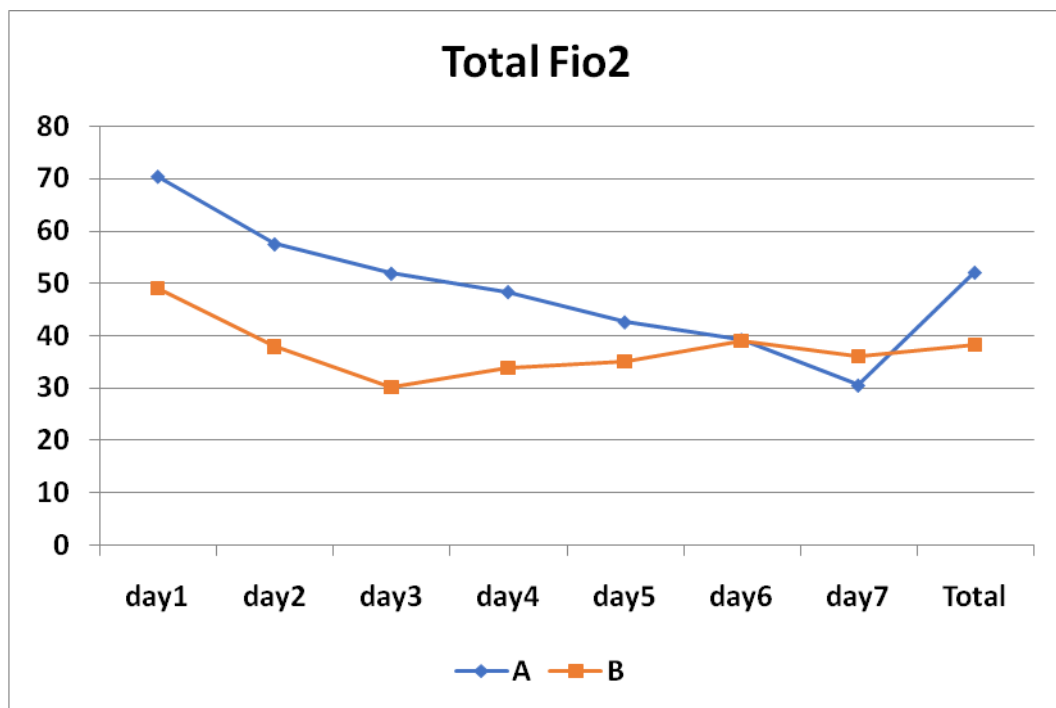
Table D.19 in appendix D: Comparisons between the study groups for the total Fio2 variables of all Shifts (N=90). The previous table's (D.19) results demonstrate that there are significant variations in Total Fio2 between the study groups (C, E) only on day1, day2, day3, and day4, and overall Total Fio2 at the 0.05 level. The findings indicate that group C's Total Fio2 levels each day are noticeably greater than group E's equivalent levels.

Day 1 data indicate that group C's Total Fio2 (mean = 70.29) is substantially greater than group E's mean (mean = 49.03), with a test P-value of 0.000. Day 2 data indicate that group C's mean Total Fio2 (mean = 57.42) is substantially greater than group E's mean (mean = 37.94); the test's P-value is 0.001. Day 3 data indicate that group C's Total Fio2 mean (mean = 51.84) is substantially greater than group E's mean (mean = 30.23), with a test P-value of 0.000. Day 4 data indicate that group C's mean Total Fio2 (mean = 48.32) is substantially greater than group E's mean (mean = 33.83); the test's P-value is 0.002.

In reference to total Fio2, the findings indicate that group C's mean (mean = 52.03) is much greater than group E's mean (mean = 38.24); the test's P-value is 0.001.

Figure 3.8

Comparisons between the study groups for the total fio2 variable .



The next table (Table D.20 in appendix D:) demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the total Set rate variables of all shifts:

Table D.20 in appendix D: Comparisons between the study groups for the total Set rate variables of all shifts (N=90).*The aforementioned (Table D.20 in appendix D:) findings demonstrate that there are only significant variations in the Total Set rate on days 1, 3, 5, and overall between the study groups (C, E) at the 0.05 level. The findings indicate that group C's daily set rate levels are noticeably greater than group E's equivalent levels.

Day 1 results indicate that group C's mean set rate (mean = 40.56) is considerably greater than group E's mean set rate (M = 34.44); the test's P-value is 0.001. Day 3 data indicate that group C's mean set rate (M = 37.05) is substantially greater than group E's mean set rate (M = 31.45); the test's P-value is 0.011. Day 5 data indicate that group C's mean set rate (M = 32.56) is substantially higher than group E's mean set rate (M = 29.23); the test's P-value is 0.016. In terms of the overall Set rate, the findings indicate that group C's mean Set rate (M = 37.21) is much greater than group E's mean (M = 32.76); the test's P-value is 0.002.

The next table (Table D.21 in appendix D) demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the total PIP variables of all shifts:

Table D.21 in appendix D: Comparisons between the study groups for the total PIP variables of all shifts (N=90).*The aforementioned table's findings demonstrate significant variations in the Total PIP on all days and between the study groups (C, E) at the 0.05 level. The findings indicate that group C's PIP levels each day are noticeably lower than group E's equivalent levels.

Day 1 data indicate that PIP in group C's mean (mean = 15.18) is substantially lower than group E's mean (mean = 18.11); the test's P-value is 0.000.

Day 2 data indicate that PIP in group C's mean (mean = 14.49) is substantially lower than group E's mean (mean = 18.17); the test's P-value is 0.000.

Day 3 data indicate that PIPin group C's mean (mean = 14.21) is substantially lower than group E's mean (mean = 16.82); the test's P-value is 0.006.

Day 4 data indicate that PIPin group C's mean (mean = 13.77) is substantially lower than group E's mean (mean = 16.41); the test's P-value is 0.002.

Day 5 data indicate that group C's PIPin mean (mean = 14) is considerably lower than group E's mean (mean = 17.33); the test's P-value is 0.001.

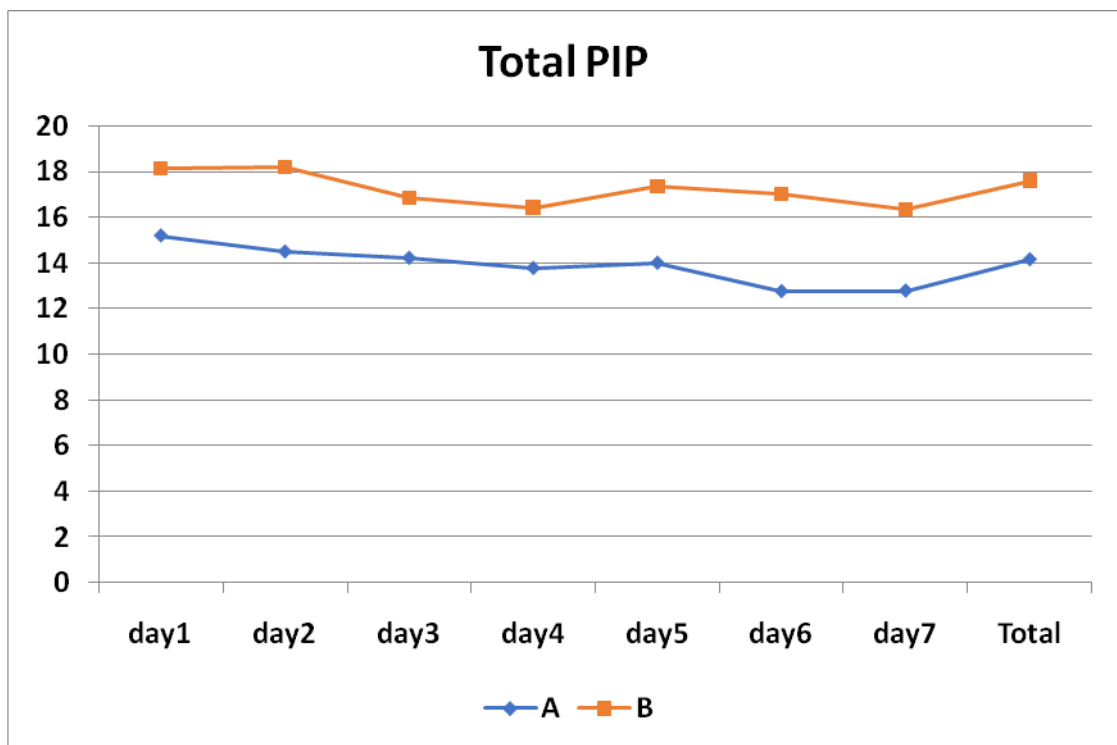
Day 6 data indicate that group C's PIPin mean (mean = 12.77) is considerably lower than group E's mean (mean = 17); the test's P-value is 0.001.

Day 7 data indicate that group C's PIPin mean (mean = 12.79) is considerably lower than group E's mean (mean = 16.33); the test's P-value is 0.025.

In terms of the overall PIP, the findings indicate that group C's mean (mean = 14.15) is substantially lower than group E's mean (mean = 17.58); the test's P-value is 0.000

Figure 3.9

Comparisons between the study groups for the total pip variable



The next table D.22 in appendix D shows the findings of the statistical testing and comparisons between the study groups (C, E) for the total PEEP variables in all shifts:

Table D.22 in appendix D: Comparisons between the study groups for the total PEEP variables in all shifts (N=90).*The results in the above table demonstrate that there are only significant differences in Total PEEP on days 4 and 6 between the study groups (C, E) at the 0.05 level. The findings indicate that group C's total PEEP levels throughout these two days were substantially lower than group E's equivalent levels. Day 4 data indicate that group C's PEEP mean (mean = 4.92) is substantially lower than group E's mean (mean = 5.25); the test's P-value is 0.019.

Day 6 data indicate that group C's PEEP mean (Mean=4.88) is much lower than group E's mean (Mean=5.22); the test's P-value is 0.021.

The next table (3.8)demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the Birth weight variable:

Table 3.8

*Comparisons between the study groups for the weight variable (N=90).**

Variable	Group						P-value
	C		E		Total		
Eirth weight	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	1972.44 ± 557.16	45	1801.13 ± 430.59	90	1886.79 ± 502.54	0.106
day2	14	2135.07 ± 436.36	44	1769.5 ± 449.42	58	1857.74 ± 469.79	0.010
day3	26	2026.19 ± 421.27	43	1766.37 ± 458.48	69	1864.28 ± 459.52	0.022
day4	19	2100.74 ± 391.15	44	1775.77 ± 456.12	63	1873.78 ± 459.69	0.009
day5	24	2045.17 ± 497.19	43	1788.19 ± 441.91	67	1880.24 ± 475.21	0.033
day6	13	2165.69 ± 430.27	43	1785.42 ± 455.83	56	1873.7 ± 474.66	0.010
day7	35	2032.54 ± 484.89	44	1797.64 ± 451.1	79	1901.71 ± 477.97	0.029
Total	45	1991.75 ± 488.99	45	1785.28 ± 442.16	90	1888.52 ± 475.02	0.039

Table D.23 in appendix D: Comparisons between the study groups for the weight variable (N=90).*The findings in the aforementioned table demonstrate that, with the exception of the first day, there are significant differences ($p < 0.05$) in weight only on all days and in total birth weight between the study groups (C, E). The findings indicate that group C's weight levels on all of these days are noticeably greater than group E's equivalent values.

Day 2 data indicate that group C's weighted mean (mean = 2135.07) is considerably higher than group E's mean (mean = 1769.5); the test's P-value is 0.010.

Day 3 data indicate that group C's weighted mean (mean = 2026.19) is considerably higher than group E's mean (mean = 1766.37), with a test P-value of 0.022.

Day 4 data indicate that group C's weighted mean (mean = 2100.74) is considerably higher than group E's mean (mean = 1775.77); the test's P-value is 0.009.

Day 5 data indicate that group C's weighted mean (mean = 2045.17) is considerably higher than group E's mean (mean = 1788.19), with a test P-value of 0.033.

Day 6 data indicate that group C's weight mean (mean = 2165.69) is substantially greater than group E's weight mean (mean = 1785.42). The test's P-value is 0.010.

Day 7 data indicate that group C's weight mean (Mean = 2032.54) is substantially greater than group E's weight mean (Mean = 1797.64); the test's P-value is 0.029.

The following table shows the results of the statistical testing and comparisons between the study groups (C, E) for the Increase in Birth weight variable:

Table 3.9

*Comparisons between the study groups for the Increase in Birth weight variable (N=90).**

Variable : Increase in Birth weight	Group			P-value
	C N(%)	E N(%)	Total N(%)	
day1	4(8.9%)	0(0%)	4(4.4%)	0.041
day2	4(28.6%)	9(20.5%)	13(22.4%)	0.526
day3	5(41.7%)	17(39.5%)	22(40%)	0.894
day4	9(75%)	24(55.8%)	33(60%)	0.230
day5	6(54.5%)	29(67.4%)	35(64.8%)	0.424
day6	3(30%)	33(76.7%)	36(67.9%)	0.004
day7	5(50%)	20(46.5%)	25(47.2%)	0.842

*The P-values are related to the Chi-square test for the qualitative or categorical variables; the numbers in the table represent N(%).

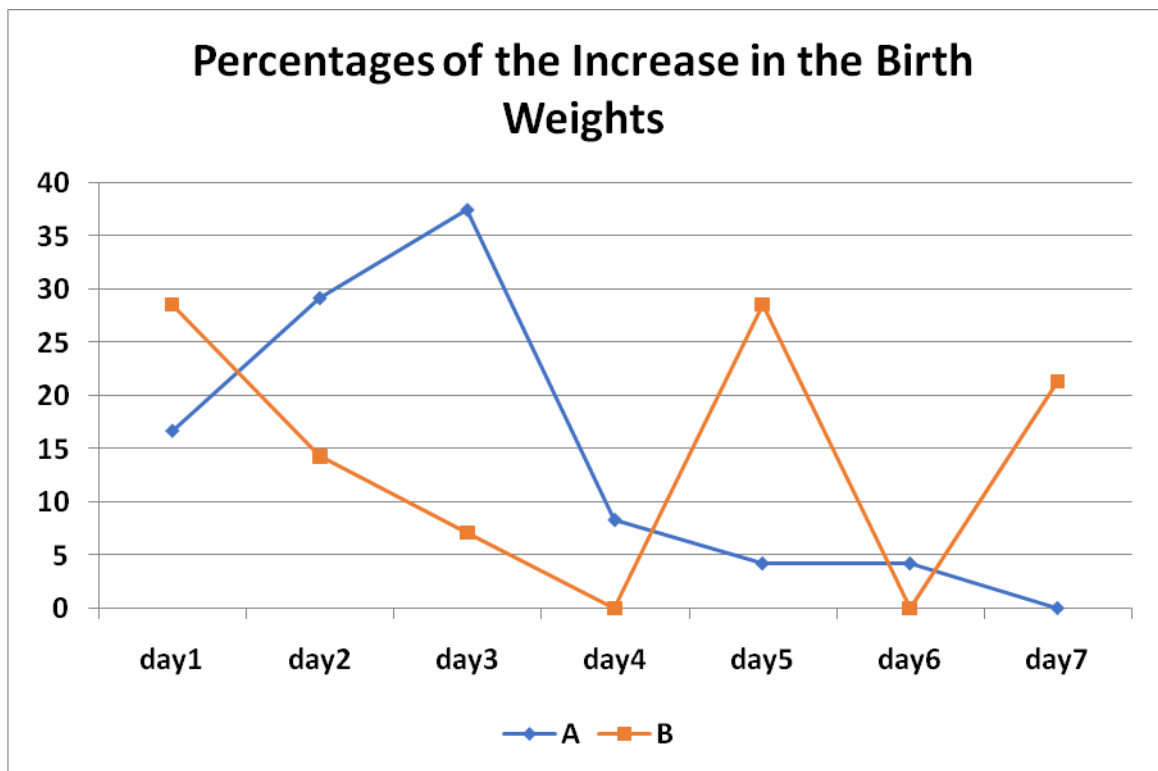
The results in the table above show that there are significant differences at 0.05 level between the study groups (C, E) in the Increase in Birth weight only on the first day and on the sixth day.

On day 1, the results show that the percentage of the increase in the Birth weight in group C (n=4, p=8.9%) is significantly higher than that in group E (n=0, p=0). The P-value of the test is 0.041. On the other hand, on day6, the results show that the percentage of the increase in the Birth weight in group C (n=3, p=30%) is significantly lower than that in group E (n=33, p=76.7), the P-value of the test is 0.004.

The results also show that the percentages of the Increase in Birth weight in the days (2, 3, 4, 7) in group C are higher than the corresponding percentages in group E, but the differences are not significant. In addition, the results show that the percentage of the Increase in Birth weight on day 5 (54.5%) in group C is lower than the corresponding percentage in group E (67.4%), but again the difference is not significant.

Figure 3.10

Percentages of the Increase in the Birth Weights



The next table D.23 in appendix D demonstrates the findings of the statistical testing and comparisons between the study groups (C, E) for the total APGAR scores in all shifts:

Table D.23 in appendix D: results in the table demonstrate that there are significant variations in the Total APGAR score only on days 1, 2, 3, and 4 between the study groups (C, E) at the 0.05 level. The findings indicate that group C's APGAR score levels are noticeably greater each day than group E's equivalent values.

Day 1 results indicate that group C's mean total APGAR score (mean = 7.47) is substantially higher than group E's mean (mean = 6.62); the test's P-value is 0.002.

Day 2 results indicate that group C's mean overall APGAR score (mean = 7.72) is substantially higher than group E's mean score (mean = 6.82); the test's P-value is 0.002.

Day 3 data indicate that group C's mean total APGAR score (mean = 7.93) is substantially higher than group E's mean score (mean = 7.43), with a test P-value of 0.039.

Day 4 data indicate that group C's mean total APGAR score (mean = 8.24) is substantially higher than group E's (mean = 7.73), with a test-day P-value of 0.029.

In terms of the overall APGAR score, the findings indicate that group C's mean score (mean = 7.47) is substantially higher than group E's (mean = 6.62); the test's P-value is 0.002.

Chapter Four

Discussion and Conclusions

The effectiveness of early enteral feeding protocols in NICUs is a critical topic in the care of very LBW preterm infants. The study compared nutrition and health outcomes in two major hospitals in Palestine, specifically Jenin Governmental Hospital and IbnSina Hospital. One of these hospitals implemented a standardized internal feeding protocol, while the others did not have such a protocol in place. Previous research in this area primarily focused on comparing necrotizing enterocolitis (NEC) outcomes. While NEC is a crucial aspect to consider, our study expanded upon these comparisons by examining a comprehensive range of factors. These factors included blood gases, vital signs, laboratory test results, residual volume, weight gain, and Apgar scores. By analyzing a broader set of parameters, we aimed to provide a more comprehensive understanding of the impact of early enteral feeding protocols on preterm clinical outcomes.

Through this discussion chapter, we will delve into the findings of our study and compare them with existing literature, particularly focusing on the unique contributions of our research in shedding light on the effectiveness of early enteral feeding protocols in improving outcomes for very low birth weight preterm infants in Palestinian NICUs.

The study that compared two groups C (late enteral feeding) and E (early enteral feeding) and found significant differences in several variables revealed that group C had higher birth weight (2006.8 vs. 1801.13, $p=0.037$), higher Apgar score1 (7.69 vs. 6.62, $p=0.000$), higher weight (2010.76 vs. 1798.02, $p=0.035$), lower total intake (119.86 vs. 536.11, $p=0.000$), and lower residual volume (9.45 vs. 21.98, $p=0.000$) compared to group E. For SBP, group C had lower levels on all days (66.11 vs. 71.22, $p=0.012$; 67.2 vs. 74.78, $p=0.000$; 69.45 vs. 74.07, $p=0.028$; 70.8 vs. 76.2, $p=0.023$; 72.05 vs. 77.98, $p=0.004$) and in total (71.09 vs. 75.35, $p=0.003$) compared to group E. Group C also had lower DBP on the first three days (36.73 vs. 41.02, $p=0.022$; 40.07 vs. 44, $p=0.022$; 39.83 vs. 43.2, $p=0.040$) compared to group E. However, group C had higher HR on selected days (144.31 vs. 135.6, $p=0.023$; 144.55 vs. 136.38, $p=0.012$; 142.26 vs. 138.43, $p=0.036$; 140.81 vs. 136.2, $p=0.033$) and in total (142.8 vs. 137.03, $p=0.025$) compared to group E. There were no significant differences in TEMP or RR

between the groups. For PLT, group C had lower levels on all days and in total (209.68 vs. 249.38, $p=0.017$; 214.31 vs. 243.22, $p=0.011$; 209.68 vs. 271.2, $p=0.000$; 212.38 vs. 260.14, $p=0.012$ 215.25 vs. 275.55, $p=0.000$;

In the current study, we examined the effects of early EF on preterm infants in Palestinian hospitals, with a sample size of 90 preterm infants split into two groups, C and E. The study population consisted of 49 males (54.4%) and 41 females (45.6%), with a mean birth weight of 1903.97 ± 468.61 grams and a mean gestational age of 32.43 ± 2.35 weeks. The mean height and weight of the preterm infants were 44.39 ± 5.17 cm and 1904.39 ± 479.68 grams, respectively. In comparison, Dr RAJESH KUMAR MEENA et al. (2024) studied 64 newborns in Group 1 (late EF) and 69 newborns in Group 2 (late EF). Their patient profile was similar to that of other studies, with varying proportions of infants appropriate for gestational age (AGA) and small for gestational age (SGA). In Krishnamurthy et al.'s study, 80% of newborns in Group 1 were AGA, while in Group 2, 72% were AGA. Karagol et al. reported 65.21% AGA newborns in Group 1 and 63.04% in Group 2. The mean gestational age in Krishnamurthy et al.'s study was 31.1 ± 1.2 weeks in Group 1 and 30.8 ± 1.1 weeks in Group 2, while in Karagol et al.'s study, it was 28.2 ± 1.1 weeks in Group 1 and 28.3 ± 1 weeks in Group 2.

1. The first hypothesis discusses if implementing an early enteral feeding protocol for preterm infants in NICU leads to improved stability of laboratory values, including BUN, Cr, Na, K, ALBUMIN, Ca, Mg, glucose, and bilirubin levels.

The results of our study support the hypothesis that implementing an early enteral feeding protocol for preterm infants leads to improved stability of laboratory values, specifically in terms of ALBUMIN levels. We found significant differences between the late feeding (Group C) and early feeding (Group E) groups, with Group C showing higher mean ALBUMIN levels compared to Group E. This suggests that early enteral feeding may contribute to better nutritional status and overall health outcomes for preterm infants. Comparing the study's findings to the study by Leaf et al. (2012), which focused on broader outcomes such as cholestatic jaundice and sepsis, we can see a similar trend toward positive effects of early enteral feeding. Leaf et al. refer to a lower incidence of cholestatic jaundice in the early feeding group, which aligns with our

findings of improved ALBUMIN levels in the early feeding group, and Al Hazzani's (2012) study found early introduction resulted in earlier establishment of full feeds, decreased cholestatic jaundice. However, differences may arise due to variations in study populations, sample sizes, feeding protocols, or other factors influencing bilirubin metabolism and liver function in premature infants.

2. The second hypothesis discusses if implementing an early enteral feeding protocol for preterm infants in NICU leads to a reduced incidence of infections in preterm infants in the NICU setting, at a significance level of P value less than 0.05.

The findings of our investigation indicate that an early EF procedure for preterm infants may result in a decreased incidence of infections, as demonstrated by the early feeding group's lower mean total white blood cell count (WBC) than the late feeding group's. This result is consistent with earlier studies conducted by Flidel-Rimon (2004), who discovered that early enteral feeding was linked to a lower risk of nosocomial sepsis (NS) among newborns that had VLBW.

Our findings, however, are in opposition to those of Young et al. (2022), who hypothesized that in extremely preterm or VLBW infants, postponing the start of progressive enteral feeds past four days after birth may not reduce the risk of necrotizing enterocolitis (NEC) or mortality. Notably, our investigation concentrated on the frequency of infections, while the studies conducted by Flidel-Rimon (2004) and Young et al. (2022) looked at more general outcomes associated with the start of enteral feeding. To completely comprehend the effect of early enteral feeding on infection rates in preterm newborns, more research is required. Infants with early enteral feedings had a lower incidence of NEC and post-NEC sequelae, according to Bjornvad et al. (2005), suggesting a possible association between early feeding and decreased infection.

3. The third hypothesis discusses if Implementing an early enteral feeding protocol for preterm infants in NICU leads to improved blood gas values (PH, PCO₂, PO₂, and HCO₃) in preterm infants in NICU at a significant level of P value less than 0.05

The study's results suggest a relationship between early enteral feeding and certain respiratory and metabolic parameters in critical preterm neonates. Specifically, we found significant differences between the study groups (C, E) in parameters such as pH,

PCO₂, PO₂, HCO₃, Total HCO₃, Total Fio₂, Total Set rate, Total PIP, and total PEEP on various days of observation. These findings indicate that early enteral feeding may have an impact on the respiratory and metabolic status of preterm neonates, potentially leading to shorter durations of mechanical ventilation and improved respiratory outcomes. In contrast, the previous study by Behnke et al. (2022) focused on the effects of rapid feeding advancement on noninvasive ventilation and growth outcomes in preterm infants. While their study did not directly assess the impact on respiratory and metabolic parameters as ours did, they found that rapid feeding advancement was associated with better stabilization on noninvasive ventilation, quicker attainment of full-volume feedings, and earlier weight regained. Importantly, they also noted no increased risk of other prematurity-related morbidities. Nangia et al. (2019) found a mean difference between the two groups regarding clinical sepsis (< 0.001), which showed less in early group feeding than in the late group. Ahmed et al., (2020) revealed that the early-feeding group had a lower incidence of neonatal sepsis than the delay group. Early enteral feeding was linked to a lower risk of nosocomial sepsis (NS), according to Flidel-Rimon (2004).

4. The fourth hypothesis discusses whether there is a significant difference in weight gain between neonates who receive early enteral feeding protocol and those who receive standard enteral feeding protocol in neonatal intensive care units in large hospitals in Palestine at the P value less than 0.05.

The results of our study indicate a significant difference in weight gain between preterm infants who received late feeding and those who followed an early enteral feeding protocol. Infants in the late-feeding group had a significantly higher mean weight than those in the early-feeding group. This finding is consistent with previous studies by Al Hazzani (2012) and Ahmed et al. (2020), which found that early introduction of enteral feeds resulted in earlier establishment of full feeds and improved weight gain. Conversely, delaying feeds leads to morbidity without benefits, as Bozkurt (2020) observed. Additionally, our study aligns with findings from Dr. RAJESH KUMAR MEENA et al. (2024), Walsh et al. (2020), Niinikoski et al. (2004), Lopez et al. (2023), and Lin et al. (2023), all of which demonstrated the positive impact of early enteral feeding on weight gain in preterm infants.

5. The fifth hypothesis discusses implementing an early enteral feeding protocol for preterm infants in NICUs leads 1st minute APGAR scores within the first 7 days of life in preterm infants in NICUs, at a significant level of P value less than 0.05.

Our study's findings indicate a significant difference in Apgar scores between infants in the late enteral feeding group (group C) and the early EFding group (group E), with the late EF group having a higher mean score. This aligns with Craft (2012) and Salas et al. (2021), who associated early enteral feeding with improved clinical outcomes and higher Apgar scores. The higher Apgar scores in the late enteral feeding group may suggest better overall health and resilience at birth compared to the early enteral feeding group. However, while Apgar scores are an important measure of newborn health, they are not the sole indicator, and further research is needed to fully understand the implications of early versus late enteral feeding on neonatal outcomes.

6. The seventh hypothesis discusses if There is a significant difference in the incidence of feeding intolerance between neonates who receive early enteral feeding protocol and those who receive standard EF protocol in neonatal intensive care units in large hospitals in Palestine at the P value less than 0.05.

Our study's findings align with previous research, showing a significant difference in residual volume between late EF (group C) and early EF (group E), with the former exhibiting a lower mean. This is consistent with studies like Morgan et al. (2019) and Leaf et al. (2012), which found that delaying enteral feeds led to a longer time for infants to achieve full EF but did not increase the risk of NEC. However, our results contrast with those of Walsh et al. (2020), who reported significant differences in feeding intolerance rates favoring early full enteral feeding. Similarly, Bozkurt et al. (2022) found no significant differences in time to reach full enteral feeding or feeding intolerance between groups. Nangia et al. (2019) also support our findings, demonstrating that early total enteral feeding (ETEF) resulted in earlier achievement of full enteral feeds compared to conventional enteral feeding (CEF). These variations highlight the need for further research to determine the optimal timing and approach to enteral feeding initiation in preterm infants.

In previous studies regarding stay in hospital, there is a significant difference in the length of hospital stay between neonates who receive rapid enteral feeding and those who receive slow enteral feeding. Rapid enteral feeding is associated with a significantly shorter duration of hospital stay, with an average of 13.63 days compared to 16.87 days for slow enteral feeding, as evidenced by studies including Young et al. (2022) and Dr. RAJESH KUMAR MEENA et al. (2024). Conversely, delayed feeding is linked to a longer duration of hospitalization, as revealed by Young et al. (2022). Additionally, early initiation of enteral feeding (<72 hours) in preterm or low birth weight infants, as demonstrated by Walsh et al. (2020), is associated with decreased mortality at discharge and 28 days. Ahmed et al. (2020) also found that the early-feeding group had shorter hospital stays than the late-feeding group. These findings align with a systematic review by Chitale et al. (2022), which showed that early initiation of enteral feeding within 72 hours after birth reduced mortality and length of hospital stay in preterm infants. Overall, these studies underscore the importance of timely initiation of enteral feeding in improving outcomes and reducing hospitalization duration in neonatal intensive care settings.

4.1 Recommendation

Based on the findings of our study comparing early and late enteral feeding protocols for preterm infants in NICUs in large hospitals in Palestine, the following recommendations are proposed for the Palestinian health system.

- Implement standardized protocols for enteral feeding of preterm infants based on best practices and current guidelines. These protocols should include criteria for initiating and advancing feeds, monitoring parameters, and criteria for discontinuation or adjustment of feeds.
- Provide regular training and education to healthcare providers involved in the care of preterm infants, including neonatologists, nurses, and dietitians. Training should focus on the latest evidence-based practices for enteral feeding and the management of feeding-related complications.

- Promote a multidisciplinary approach to the care of preterm infants, involving collaboration between neonatologists, nurses, dietitians, and other healthcare professionals. This approach can ensure comprehensive care and optimal outcomes for preterm infants.
- Encourage parental involvement in the care of preterm infants, including participation in feeding decisions and care. Providing education and support to parents can empower them to be active participants in their infant's care.
- Establish regular monitoring and evaluation mechanisms to assess the effectiveness of enteral feeding protocols and identify areas for improvement. This can include tracking key outcomes such as feeding tolerance, growth, and development.
- Ensure adequate allocation of resources, including equipment, staffing, and training, to support the implementation of enteral feeding protocols in NICUs. Adequate resources are essential for providing high-quality care to preterm infants.
- Encourage and support research and innovation in the field of neonatal care, including enteral feeding practices. Continued research can lead to the development of new and improved strategies for preterm feeding infants and improving outcomes.
- Establish quality improvement programs focused on enhancing the quality and safety of enteral feeding practices in NICUs. These programs should involve regular audits, feedback, and adjustments to protocols based on findings.

4.2 Limitations

1. There is a scarcity of studies that have compared early enteral feeding protocol and latent feeding regarding many variables such as ABGs, lab tests, and vital signs.
2. The study included Jenin Governmental Hospital and IbnSina only, and we did not have the opportunity to include a larger number of hospitals to generalize the study further, due to the difficulty of movement between governorates due to political and security events.
3. Sample Size: The sample size in this study was relatively small, which may limit the statistical power of the findings. Larger studies are needed to confirm the results.

4. One of the main challenges that I, as a researcher, experienced during this study was the restriction of being present in all the shifts due to the political situation at the time of data collection and checkpoints. Thus, the researcher kept in consistent touch with the nurse staff when the premature baby arrived at the nursery.

4.3 Conclusion

Based on our study comparing the outcomes of preterm infants receiving an early enteral feeding protocol to those receiving routine care without the protocol, with a sample size of 90 infants in total, we can draw several conclusions regarding the effectiveness of early enteral feeding on preterm clinical outcomes in neonatal intensive care units (NICUs) in a large hospital in Palestine. Firstly, the implementation of an early enteral feeding protocol within 24 hours of birth in preterm infants admitted to the NICU at Government Hospital and IbnSina Hospital in Jenin showed significant positive impacts on various clinical parameters. Group E, receiving the early enteral feeding protocol, demonstrated lower mean values in total systolic blood pressure, total platelet count, total calcium, total bilirubin, total bicarbonate, total Fio₂, and total PIP compared to Group C (routine care without the protocol). These findings suggest that early enteral feeding may contribute to better cardiovascular, hematological, and respiratory stability in preterm infants. However, it's important to note that Group C showed higher mean values in total heart rate, total white blood cell count, and total Fio₂, suggesting potential variations in physiological responses between the two groups.

Overall, this study, with a sample size of 90 preterm infants, provides evidence supporting the effectiveness of early enteral feeding protocols in improving preterm clinical outcomes in NICUs at Government Hospital and PraivetHospital in Jenin, Palestine. Implementing early enteral feeding protocols may lead to improved outcomes and clinical stability in preterm infants, reducing the length of stay in the hospital and contributing to enhanced overall health outcomes during their neonatal period. These findings underscore the importance of early nutritional interventions in preterm care strategies, with potential implications for improving long-term health trajectories in this vulnerable population.

List of Abbreviations

Abbreviation	Meaning
ANOVA	Analysis of variance
GI	Gastrointestinal
GRV	Gastric residual volume
IRP	Institutional review board
LOS	Length of stay
NEC	Necrotizing enterocolitis
NNICU	Neonate intensive care unit
NPO	Nil per os (nothing by mouth)
NG	Nasogastric
PPN	Peripheral parentera nutrition
PEEP	Positive end- expiratory pressure
RCT	Randomize control trial
SPSS	Statistical package for the social science
TPN	Total parenteral nutrition
TV	Tidal volume

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Appendices

Appendix A

Consent form

طلب موافقة على المشاركة في بحث علمي

عزيزي/تي المُشارك/ة :

أنا الطالبة اشتياق حاتم صالح حمدان، أدرس ماجستير تمريض عناية مكثفة بكلية الدراسات العليا، في

جامعة النجاح الوطنية

أقوم بإعداد بحث بعنوان:

فعالية بروتوكول التغذية المعوية المبكرة على النتائج السريرية في وحدات العناية المركزة لحديثي الولادة في

مستشفى كبير في فلسطين.

باعتباره متطلب للتخرج والحصول على درجة الماجستير، وتم اختيار طفلك بناءً على مطابقته لشروط

العينة.

بالتوقيع أدناه ، فإنك تشير إلى أنك قد قرأت وفهمت المعلومات الواردة في نموذج الموافقة هذا. أنت توافق

طواعية على السماح لطفلك بالمشاركة في الدراسة وتقر بأنه يمكنك سحب مشاركة طفلك في أي وقت .

توقيع المشارك: _____ التاريخ _____ :

توقيع ولي الأمر / الوصي القانوني: _____ التاريخ _____ :

توقيع الباحث: _____ التاريخ _____ :

ملاحظة: سيتم تزويدك بنسخة من نموذج الموافقة هذا للاحتفاظ بها في سجلاتك

سنزودك بمعلومات مفصلة عن الدراسة، بما في ذلك الغرض منها وإجراءاتها والمخاطر والفوائد المحتملة

لديك الحق في طرح الأسئلة وتوضيح أي مخاوف قبل اتخاذ قرار المشاركة.

Appendix B

Data Collection Tool

The flowchart will also include a timeline where different variables are measured such as APGAR score, weight, height, head circumference, blood gas, lab test, mechanical ventilator settings, feeding intake, residual volume, output, and complications.

1. Socio-demographic characteristics of neonates admitted in NICU of Variables Categories Gestational age in week Birth weight in gram maternal age.

1- Participant no	
2- Gender	
3- Birth weight	
4- Gestational age, weeks	
5- Apgar Score	
6. Weight	
7..Date of admission	

Section 2: Feeding

Intake DAILY		Residual volume	
Type	Amount	Time	Amount
Total intake =			

**Section 3: Check the following daily for 7 days or until discharge from ICU:
V/S, Lab test and mechanical ventilator**

	Vital sign	BP	HR	TEMP	RR	CVP
Day						
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						

Lab test	HGB	PLT	BUN	Cr	Na	K	ALBUMINE	WBC	Ca	Mg	Glucose	BILIRUBIN
Day												
Day 1												
Day 2												
Day 3												
Day 4												
Day 5												
Day 6												
Day 7												

Day \	Blood gas	PH	PCO2	PO2	HCO3
Day 1					
Day 2					
Day 3					
Day 4					
Day 5					
Day 6					
Day 7					

Day \	Mechanical ventilator	Mode		Fio2			Set rate		TV		PEEP		
		A	B	ABC			A	B	A	B	A	B	
		C					C		C		C		
Day1													
Day2													
Day3													
Day4													
Day5													
Day6													
Day7													

Section four :Birth weight for 7 days

Day \	Birth weight			
Day1				
Day2				
Day3				
Day4				
Day5				
Day6				
Day7				

Section five :1st minute APGAR score for 7 days

APGAR score Day				
Day1				
Day2				
Day3				

Day4				
Day5				
Day6				
Day7				

Appendix C

IRB

An-Najah National
University
Faculty of Medicine &
Health Sciences
Institutional Review Board



جامعة النجاح الوطنية
كلية الطب وعلوم الصحة
لجنة أخلاقيات البحث العلمي

Ref : Mas. 2023/25

IRB Approval Letter

Title of Research:

The effectiveness of early enteral feeding protocol on preterm clinical outcomes in neonatal intensive care units in large hospital in Palestine

Submitted by:

Eshtyaq Hatem Saleh Hamdan

Supervisor:

Rman Alshawish

Approved:

19th June, 2023

Your Study Title "The effectiveness of early enteral feeding protocol on preterm clinical outcomes in neonatal intensive care units in large hospital in Palestine." reviewed by An-Najah National University IRB committee and was approved on 19th , June . 2023


Hasan Fitian, MD

IRB Committee Chairman



Appendix D

Tables of Study

Table D.1

*Comparisons between the study groups for the SBP variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	66.11 ± 7.21	45	71.22 ± 11.18	90	68.67 ± 9.7	0.012
day2	44	67.2 ± 9.94	45	74.78 ± 9.41	89	71.03 ± 10.35	0.000
day3	42	69.45 ± 11.08	44	74.07 ± 7.92	86	71.81 ± 9.81	0.028
day4	41	70.8 ± 10.72	44	76.2 ± 10.71	85	73.6 ± 10.99	0.023
day5	41	72.05 ± 10.6	44	77.98 ± 7.46	85	75.12 ± 9.53	0.004
day6	40	74.4 ± 9.56	43	74.93 ± 8.79	83	74.67 ± 9.11	0.793
day7	40	76.63 ± 9.16	43	76.37 ± 7.29	83	76.49 ± 8.19	0.889
Total	45	71.09 ± 7.24	45	75.35 ± 6.16	90	73.22 ± 7.02	0.003

Table D.2

*Comparisons between the study groups for the DBP variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	36.73 ± 8.19	45	41.02 ± 9.16	90	38.88 ± 8.91	0.022
day2	44	40.07 ± 8.17	45	44 ± 7.72	89	42.06 ± 8.14	0.022
day3	42	39.83 ± 8.62	44	43.2 ± 6.23	86	41.56 ± 7.64	0.040
day4	41	42.95 ± 10.36	44	43.55 ± 7.28	85	43.26 ± 8.85	0.759
day5	41	44.27 ± 7.67	44	43.55 ± 5.57	85	43.89 ± 6.64	0.619
day6	40	45.8 ± 7.55	43	44.07 ± 9.37	83	44.9 ± 8.54	0.359
day7	40	45.63 ± 7.39	43	44.28 ± 7.25	83	44.93 ± 7.3	0.405
Total	45	41.86 ± 5.37	45	43.64 ± 4.06	90	42.75 ± 4.82	0.081

Table D.3*Comparisons between the study groups for the TEMP variable (N=90).**

Variable : TEMP	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	36.53 ± 0.55	45	36.33 ± 0.87	90	36.43 ± 0.73	0.185
day2	38	36.58 ± 0.39	45	36.54 ± 0.72	83	36.56 ± 0.59	0.760
day3	37	36.5 ± 0.39	44	36.66 ± 0.48	81	36.59 ± 0.45	0.107
day4	41	36.54 ± 0.36	44	36.63 ± 0.45	85	36.59 ± 0.41	0.324
day5	38	36.54 ± 0.37	44	36.56 ± 0.46	82	36.55 ± 0.42	0.793
day6	35	36.53 ± 0.31	43	36.67 ± 0.42	78	36.61 ± 0.38	0.118
day7	39	36.51 ± 0.3	43	36.64 ± 0.75	82	36.58 ± 0.58	0.299
Total	45	36.57 ± 0.36	45	36.61 ± 0.45	90	36.59 ± 0.41	0.694

Table D.4*Comparisons between the study groups for the RR variable (N=90).**

Variable : RR	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	44	50.3 ± 5.3	45	50.49 ± 6	89	50.39 ± 5.64	0.872
day2	43	50.12 ± 5.06	45	49.78 ± 5.48	88	49.94 ± 5.25	0.764
day3	42	48.74 ± 5.1	44	48.8 ± 3.91	86	48.77 ± 4.5	0.953
day4	41	48.24 ± 4.81	44	48.89 ± 3.6	85	48.58 ± 4.21	0.486
day5	41	47.85 ± 5.27	44	48.45 ± 3.87	85	48.16 ± 4.58	0.549
day6	41	47.9 ± 4.37	43	47.98 ± 3.62	84	47.94 ± 3.98	0.932
day7	41	47.66 ± 4.72	43	48.56 ± 4.33	84	48.12 ± 4.52	0.365
Total	44	48.99 ± 4.03	45	49.2 ± 3.82	89	49.09 ± 3.9	0.800

Table D.5*Comparisons between the study groups for the HGB variable (N=90).**

Variable : HGB	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	44	15.19 ± 2.79	45	14.77 ± 2.52	89	14.98 ± 2.65	0.465
day2	35	14.65 ± 2.24	45	14.36 ± 2.27	80	14.49 ± 2.25	0.564
day3	36	14.37 ± 2.11	44	13.68 ± 2.48	80	13.99 ± 2.33	0.193
day4	24	13.38 ± 2.25	44	13.67 ± 1.86	68	13.57 ± 2	0.575
day5	29	13.14 ± 2.27	43	13.3 ± 1.84	72	13.23 ± 2.01	0.747
day6	28	15.58 ± 15.14	43	15.43 ± 16.91	71	15.49 ± 16.13	0.969
day7	30	13.05 ± 1.59	42	12.9 ± 1.49	72	12.96 ± 1.52	0.683
Total	44	14.21 ± 2.86	45	13.93 ± 2.91	89	14.06 ± 2.87	0.648

Table D.6*Comparisons between the study groups for the PLT variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
PLT							
day1	44	209.68 ± 80.23	45	249.38 ± 73.93	89	229.75 ± 79.23	0.017
day2	35	214.31 ± 85.33	45	243.22 ± 57.2	80	230.58 ± 71.86	0.011**
day3	37	209.68 ± 65.27	44	271.2 ± 59.2	81	243.1 ± 68.93	0.000
day4	26	212.38 ± 70.04	44	260.14 ± 77.28	70	242.4 ± 77.71	0.012
day5	28	215.25 ± 64.27	44	275.55 ± 70.59	72	252.1 ± 73.93	0.000
day6	26	202.58 ± 71.11	43	292.21 ± 104.72	69	258.43 ± 102.69	0.000
day7	27	199.67 ± 58.88	42	286.64 ± 74.11	69	252.61 ± 80.41	0.000
Total	44	217.16 ± 70.72	45	265 ± 49.07	89	241.35 ± 65.01	0.000

Table D.7*Comparisons between the study groups for the BUN variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
BUN							
day1	36	19.02 ± 8.87	45	15.29 ± 5.96	81	16.95 ± 7.58	0.027
day2	28	19.37 ± 7.64	45	16.73 ± 8.26	73	17.74 ± 8.08	0.176
day3	23	20.36 ± 10.26	44	17.37 ± 8.38	67	18.4 ± 9.1	0.204
day4	16	23.91 ± 13.52	43	15.43 ± 7.68	59	17.73 ± 10.22	0.004
day5	13	19.39 ± 8.31	43	15.55 ± 6.41	56	16.44 ± 7.01	0.083
day6	13	21.8 ± 9.37	42	16.15 ± 9.72	55	17.49 ± 9.85	0.008
day7	15	20.5 ± 11.07	41	13.9 ± 6.52	56	15.67 ± 8.41	0.008
Total	45	19.15 ± 8.14	45	15.94 ± 6.38	90	17.55 ± 7.45	0.040

Table D.8*Comparisons between the study groups for the Cr variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
Cr							
day1	36	0.82 ± 0.25	45	0.76 ± 0.32	81	0.79 ± 0.29	0.389
day2	30	1 ± 1.03	45	0.84 ± 0.66	75	0.91 ± 0.83	0.434
day3	24	0.76 ± 0.18	44	0.76 ± 0.73	68	0.76 ± 0.6	0.957
day4	13	2.26 ± 5.33	44	0.97 ± 1.55	57	1.26 ± 2.87	0.156
day5	17	1.13 ± 2.04	43	0.65 ± 0.15	60	0.78 ± 1.09	0.127
day6	13	0.74 ± 0.26	42	0.75 ± 0.77	55	0.75 ± 0.68	0.983
day7	15	0.67 ± 0.25	41	0.8 ± 0.99	56	0.77 ± 0.85	0.622
Total	45	0.99 ± 1.18	45	0.81 ± 0.69	90	0.9 ± 0.97	0.371

Table D.9*Comparisons between the study groups for the Na variable (N=90).**

Variable : Na	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	39	137.26 ± 5.66	45	135.61 ± 6.82	84	136.38 ± 6.33	0.237
day2	27	138.93 ± 6.28	45	136.25 ± 4.85	72	137.25 ± 5.54	0.046
day3	17	138.82 ± 7.66	44	137.85 ± 4.63	61	138.12 ± 5.59	0.544
day4	13	138.46 ± 6.89	44	137.48 ± 4.9	57	137.71 ± 5.36	0.568
day5	16	138.88 ± 5.51	44	137.25 ± 3.86	60	137.69 ± 4.37	0.206
day6	14	140 ± 4.74	43	137 ± 4.24	57	137.74 ± 4.52	0.030
day7	16	132.44 ± 26.06	42	138.12 ± 6.88	58	136.55 ± 14.81	0.194
Total	45	137.7 ± 5.54	45	136.96 ± 2.98	90	137.33 ± 4.44	0.433

Table D.10*Comparisons between the study groups for the K variable (N=90).**

Variable : K	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	36	4.76 ± 0.69	45	4.47 ± 0.84	81	4.6 ± 0.79	0.099
day2	26	4.87 ± 0.78	45	4.43 ± 0.62	71	4.59 ± 0.71	0.011
day3	16	4.3 ± 0.67	44	4.36 ± 0.72	60	4.35 ± 0.7	0.763
day4	11	4.4 ± 0.63	44	4.31 ± 0.72	55	4.33 ± 0.7	0.714
day5	15	4.19 ± 0.46	44	4.2 ± 0.87	59	4.2 ± 0.78	0.961
day6	12	6.58 ± 8.34	43	4.36 ± 1.04	55	4.85 ± 3.98	0.089
day7	16	4.29 ± 0.46	42	4.39 ± 1.04	58	4.36 ± 0.91	0.707
Total	43	4.76 ± 1.55	45	4.36 ± 0.64	88	4.56 ± 1.19	0.021

Table D.11*Comparisons between the study groups for the ALBUMINE variable (N=90).**

Variable : ALBUMINE	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	9	12.05 ± 12.95	2	2.56 ± 0.79	11	10.32 ± 12.2	0.346
day2	5	3.68 ± 1.12	1	1.7 ± 0	6	3.35 ± 1.28	0.181
day3	5	8.34 ± 9.35	1	1.7 ± 0	6	7.23 ± 8.79	0.552
day4	3	2.84 ± 0.84	1	1.5 ± 0	4	2.51 ± 0.96	0.303
day5	3	2.8 ± 0.1	1	1.5 ± 0	4	2.48 ± 0.66	0.008
day6	2	2.5 ± 0.28	1	1.2 ± 0	3	2.07 ± 0.78	0.166
day7	3	3 ± 0	1	1.3 ± 0	4	2.58 ± 0.85	0.253
Total	15	8.88 ± 10.86	2	2.34 ± 1.11	17	8.11 ± 10.39	0.040**

Table D.12*Comparisons between the study groups for the Ca variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
Ca	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	27	6.03 ± 2.14	45	6.82 ± 1.38	72	6.52 ± 1.73	0.028
day2	23	6.67 ± 2.36	45	7.27 ± 1.73	68	7.07 ± 1.97	0.236
day3	20	6.33 ± 3.25	44	7.6 ± 1.87	64	7.21 ± 2.43	0.052
day4	12	6.67 ± 2.83	44	7.57 ± 1.93	56	7.38 ± 2.16	0.201
day5	15	6.77 ± 2.71	44	7.76 ± 1.61	59	7.51 ± 1.97	0.093
day6	7	8.31 ± 2.94	42	8.04 ± 1.23	49	8.08 ± 1.55	0.666
day7	16	6.84 ± 2.62	41	8.21 ± 1.13	57	7.83 ± 1.77	0.007
Total	38	6.66 ± 2.34	45	7.58 ± 0.96	83	7.16 ± 1.78	0.018

Table D.13*Comparisons between the study groups for the Glucose variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
Glucose	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	43	85.49 ± 23.56	43	91.7 ± 31.62	86	88.59 ± 27.89	0.305
day2	30	95.13 ± 23.05	43	99.3 ± 34.54	73	97.59 ± 30.24	0.566
day3	32	96.78 ± 23.51	42	103.24 ± 29.84	74	100.45 ± 27.3	0.317
day4	30	108.37 ± 41.72	42	100.43 ± 27.11	72	103.74 ± 33.92	0.331
day5	28	95.89 ± 16.71	42	103 ± 27.76	70	100.16 ± 24.07	0.228
day6	29	98.41 ± 18.42	42	99.5 ± 22.17	71	99.06 ± 20.59	0.829
day7	31	101.35 ± 16.09	41	99.12 ± 22.63	72	100.08 ± 19.98	0.642
Total	43	94.96 ± 18.2	43	98.8 ± 20.13	86	96.88 ± 19.17	0.355

Table D.14*Comparisons between the study groups for the BILIRUBIN variable (N=90).**

Variable :	Group						P-value
	C		E		Total		
BILIRUBIN	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	32	10.79 ± 6	44	7.16 ± 1.54	76	8.69 ± 4.42	0.000
day2	22	11.25 ± 6.62	44	6.82 ± 1.82	66	8.29 ± 4.56	0.000
day3	24	10.57 ± 7.62	43	7.2 ± 2.03	67	8.41 ± 5.05	0.008
day4	19	11.36 ± 6.43	43	7.47 ± 1.86	62	8.66 ± 4.22	0.001
day5	21	10.82 ± 5.65	43	7.53 ± 1.36	64	8.61 ± 3.71	0.001
day6	19	10.25 ± 6.34	42	6.57 ± 2.1	61	7.72 ± 4.25	0.001
day7	20	10 ± 6.2	40	6.59 ± 2.36	60	7.72 ± 4.32	0.003
Total	40	9.32 ± 5.1	44	7.02 ± 1.33	84	8.11 ± 3.8	0.005

Table D.15*Comparisons between the study groups for the PH variable (N=90).**

Variable : PH	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	7.29 ± 0.14	45	7.31 ± 0.12	90	7.3 ± 0.13	0.520
day2	39	7.32 ± 0.1	45	7.37 ± 0.08	84	7.34 ± 0.09	0.010
day3	40	7.33 ± 0.07	44	7.37 ± 0.08	84	7.35 ± 0.08	0.004
day4	36	7.33 ± 0.08	44	7.36 ± 0.06	80	7.35 ± 0.07	0.119
day5	38	7.35 ± 0.08	44	7.37 ± 0.07	82	7.36 ± 0.08	0.499
day6	36	7.38 ± 0.08	43	7.37 ± 0.09	79	7.38 ± 0.08	0.773
day7	37	7.42 ± 0.08	40	7.39 ± 0.08	77	7.4 ± 0.08	0.214
Total	45	7.34 ± 0.07	45	7.36 ± 0.04	90	7.35 ± 0.06	0.119

Table D.16*Comparisons between the study groups for the PCO2 variable (N=90).**

Variable : PCO2	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	43.42 ± 10.63	45	42.52 ± 12.68	90	42.97 ± 11.65	0.716
day2	39	40.09 ± 9.8	45	38.59 ± 9.68	84	39.29 ± 9.7	0.481
day3	40	43.15 ± 12.53	44	39.03 ± 7.38	84	40.99 ± 10.3	0.067
day4	36	41.19 ± 7.96	44	37.61 ± 6.68	80	39.22 ± 7.46	0.032
day5	38	40.27 ± 12	44	38.13 ± 7.96	82	39.12 ± 10.03	0.338
day6	36	40.03 ± 11.79	43	38.69 ± 8.96	79	39.3 ± 10.3	0.568
day7	36	38.01 ± 10.1	40	38.96 ± 7.88	76	38.51 ± 8.95	0.646
Total	45	40.72 ± 7.32	45	39.41 ± 6.28	90	40.06 ± 6.81	0.365

Table D.17*Comparisons between the study groups for the PO2 variable (N=90).**

Variable : PO2	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	87.06 ± 36.01	45	99.81 ± 44.56	90	93.44 ± 40.79	0.139
day2	39	84.82 ± 26.11	45	79.64 ± 33.19	84	82.04 ± 30.04	0.433
day3	39	84.63 ± 23.37	44	75.63 ± 24.68	83	79.86 ± 24.35	0.035
day4	36	85.62 ± 24.56	44	88.58 ± 34.71	80	87.25 ± 30.42	0.668
day5	37	98.58 ± 25.74	44	92.52 ± 36.43	81	95.29 ± 31.95	0.399
day6	36	99.01 ± 25.08	43	99.59 ± 37.36	79	99.32 ± 32.15	0.937
day7	37	95.45 ± 19.91	40	88.09 ± 32.26	77	91.63 ± 27.12	0.237
Total	45	90.17 ± 19.32	45	88.5 ± 21.17	90	89.33 ± 20.17	0.697

Table D.18*Comparisons between the study groups for the HCO₃ variable (N=90).**

Variable : HCO ₃	Group						P-value
	C		E		Total		
	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	44	18.66 ± 5	45	21.22 ± 6.4	89	19.96 ± 5.86	0.038
day2	39	18.33 ± 4.81	45	21.24 ± 5.22	84	19.89 ± 5.21	0.010
day3	40	18.8 ± 4.3	44	22.01 ± 3.96	84	20.48 ± 4.4	0.001
day4	36	18.82 ± 4.17	44	22.1 ± 3.9	80	20.63 ± 4.32	0.001
day5	38	19.69 ± 4.43	44	21.44 ± 3.65	82	20.63 ± 4.1	0.053
day6	36	19.92 ± 3.94	43	22.45 ± 3.4	79	21.3 ± 3.85	0.003
day7	37	21.31 ± 4.65	40	23.48 ± 3.38	77	22.44 ± 4.16	0.021
Total	45	19.82 ± 3.95	45	21.82 ± 3.38	90	20.82 ± 3.79	0.012

Table D.19*Comparisons between the study groups for the total Fio₂ variables of all Shifts (N=90).**

Variable : Total Fio ₂ of all Shifts	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	35	70.29 ± 28.38	38	49.03 ± 17.49	73	59.22 ± 25.53	0.000
day2	32	57.42 ± 26.78	36	37.94 ± 16.23	68	47.11 ± 23.78	0.000
day3	30	51.84 ± 21.65	30	30.23 ± 10.53	60	41.04 ± 20.09	0.000
day4	29	48.32 ± 19.63	23	33.83 ± 9.63	52	41.91 ± 17.45	0.002
day5	26	42.58 ± 17.03	15	35.07 ± 10.42	41	39.83 ± 15.25	0.130
day6	22	39.21 ± 16.89	10	39 ± 15.78	32	39.15 ± 16.3	0.973
day7	20	30.53 ± 6.83	5	36 ± 6.52	25	31.63 ± 7	0.120
Total	35	52.03 ± 20.45	38	38.24 ± 13.01	73	44.85 ± 18.24	0.001

Table D.20*Comparisons between the study groups for the total Set rate variables of all shifts (N=90).**

Variable : Total Set rate of all Shifts	Group						P-value
	C		E		Total		
	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	26	40.56 ± 5.94	36	34.44 ± 7.73	62	37.01 ± 7.62	0.001
day2	24	38.92 ± 5.66	31	36.29 ± 6.58	55	37.44 ± 6.28	0.125
day3	26	37.05 ± 6.42	22	31.45 ± 8.26	48	34.49 ± 7.77	0.011
day4	19	33.6 ± 6.49	17	31.94 ± 4.78	36	32.81 ± 5.72	0.394
day5	13	32.56 ± 5.59	13	29.23 ± 1.88	26	30.9 ± 4.43	0.016
day6	11	31.82 ± 5.13	5	32 ± 5.7	16	31.88 ± 5.12	0.950
day7	10	31 ± 5.68	3	33.33 ± 5.77	13	31.54 ± 5.55	0.546
Total	28	37.21 ± 5.88	38	32.76 ± 5.4	66	34.64 ± 5.99	0.002

Table D.21*Comparisons between the study groups for the total PIP variables of all shifts(N=90).**

Variable :	Group						P-value
	C		E		Total		
Total PIP of all Shifts	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	31	15.18 ± 3.79	36	18.11 ± 2.11	67	16.76 ± 3.33	0.000
day2	28	14.49 ± 3.91	30	18.17 ± 1.86	58	16.39 ± 3.53	0.000
day3	28	14.21 ± 3.62	22	16.82 ± 2.56	50	15.36 ± 3.42	0.006
day4	22	13.77 ± 2.94	17	16.41 ± 1.46	39	14.92 ± 2.73	0.002
day5	16	14 ± 2.31	12	17.33 ± 2.1	28	15.43 ± 2.75	0.001
day6	13	12.77 ± 2.28	6	17 ± 2	19	14.11 ± 2.94	0.001
day7	13	12.79 ± 2.83	3	16.33 ± 1.53	16	13.46 ± 2.96	0.025
Total	32	14.15 ± 3.39	38	17.58 ± 1.98	70	16.01 ± 3.2	0.000

Table D.22*Comparisons between the study groups for the total PEEP variables in all shifts(N=90).**

Variable :	Group						P-value
	C		E		Total		
Total PEEP of all Shifts	n	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	32	5.56 ± 0.67	38	5.51 ± 0.6	70	5.54 ± 0.63	0.747
day2	31	5.29 ± 0.61	36	5.39 ± 0.55	67	5.34 ± 0.58	0.490
day3	28	5.15 ± 0.55	28	5.93 ± 3.95	56	5.54 ± 2.82	0.309
day4	27	4.92 ± 0.47	20	5.25 ± 0.44	47	5.06 ± 0.49	0.019
day5	22	5.13 ± 0.61	14	5.21 ± 0.43	36	5.16 ± 0.54	0.650
day6	17	4.88 ± 0.26	9	5.22 ± 0.44	26	5 ± 0.37	0.021
day7	16	4.81 ± 0.4	7	5.14 ± 0.38	23	4.91 ± 0.42	0.080
Total	32	5.16 ± 0.44	38	5.42 ± 0.62	70	5.3 ± 0.56	0.058

Table D.23*Comparisons between the study groups for the for the total APGAR scores in all shifts (N=90).**

Variable :	Group						P-value
	C		E		Total		
Total APGAR score of all Shifts	N	Mean ± S.D	n	Mean ± S.D	n	Mean ± S.D	
day1	45	7.47 ± 1.28	45	6.62 ± 1.19	90	7.05 ± 1.3	0.002
day2	45	7.72 ± 1.26	45	6.82 ± 1.34	90	7.27 ± 1.37	0.002
day3	45	7.93 ± 1.16	44	7.43 ± 1.09	89	7.69 ± 1.15	0.039
day4	43	8.24 ± 1.05	44	7.73 ± 1.11	87	7.98 ± 1.1	0.029
day5	43	8.39 ± 1.02	44	8.14 ± 1.09	87	8.26 ± 1.06	0.271
day6	43	8.47 ± 0.93	44	8.41 ± 0.9	87	8.44 ± 0.91	0.775
day7	43	8.51 ± 1.05	44	8.61 ± 0.75	87	8.56 ± 0.91	0.603
Total	45	7.47 ± 1.28	45	6.62 ± 1.19	90	7.05 ± 1.3	0.002

*The P-values are related to the two independent samples T-test for the quantitative variables; the numbers in the table represent (Mean ± Standard deviation).

Appendix E
Figures of study

Figure E.1

Comparisons between the study groups for the SBP variable

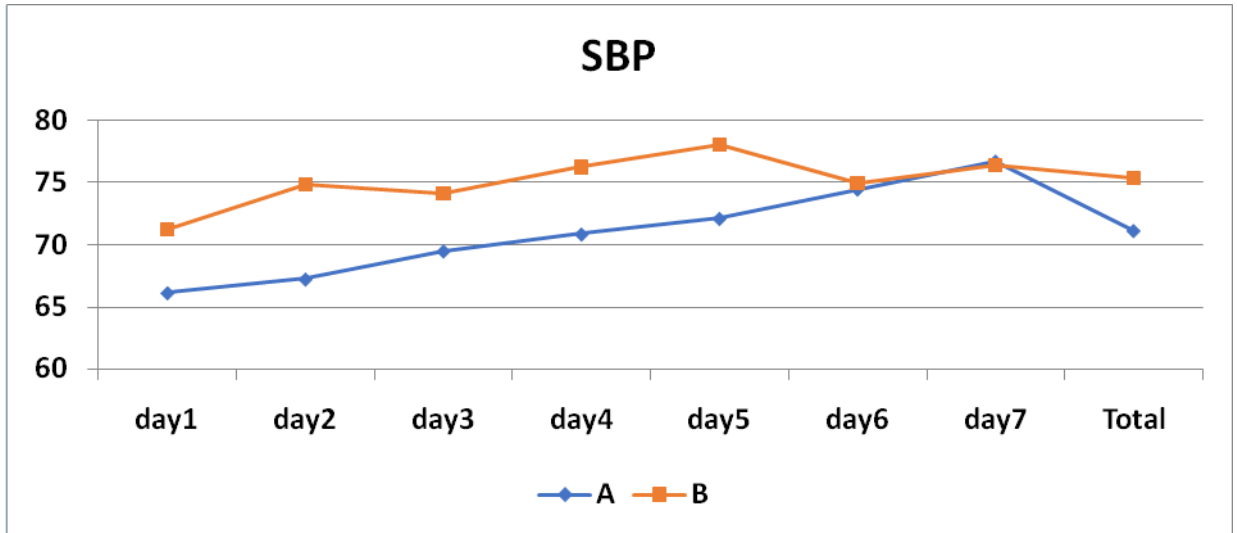


Figure E.2

Comparisons between the study groups for the DBP variable

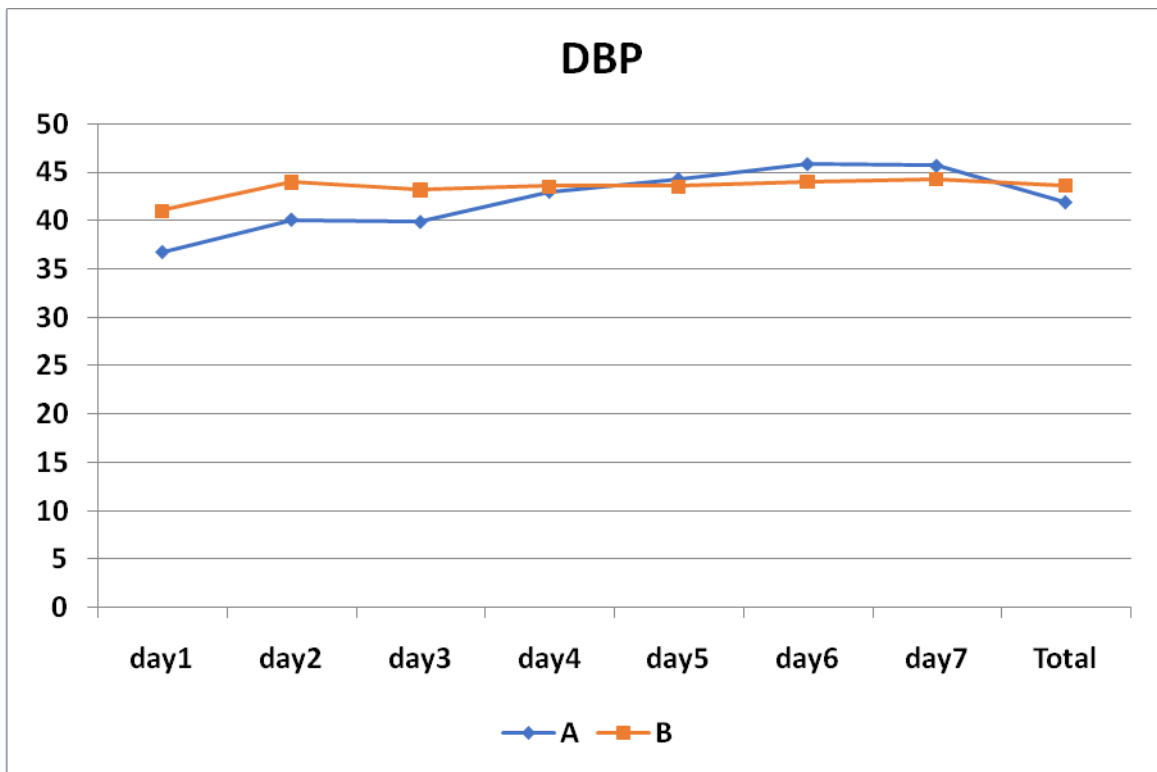


Figure E.3

Comparisons between the study groups for the TEMP variable

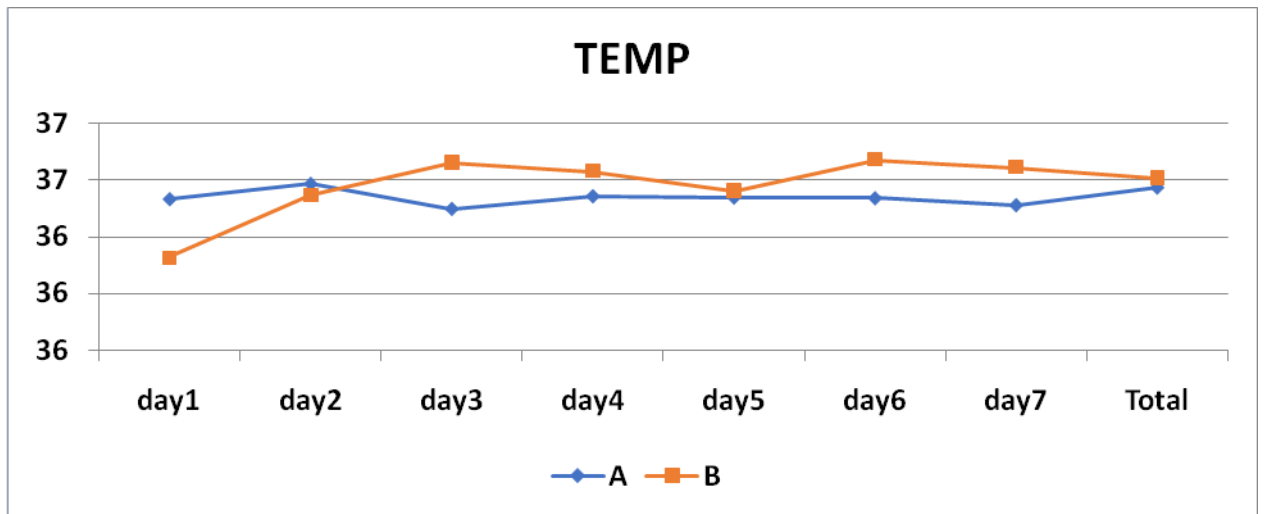


Figure E.4

Comparisons between the study groups for the RR variable

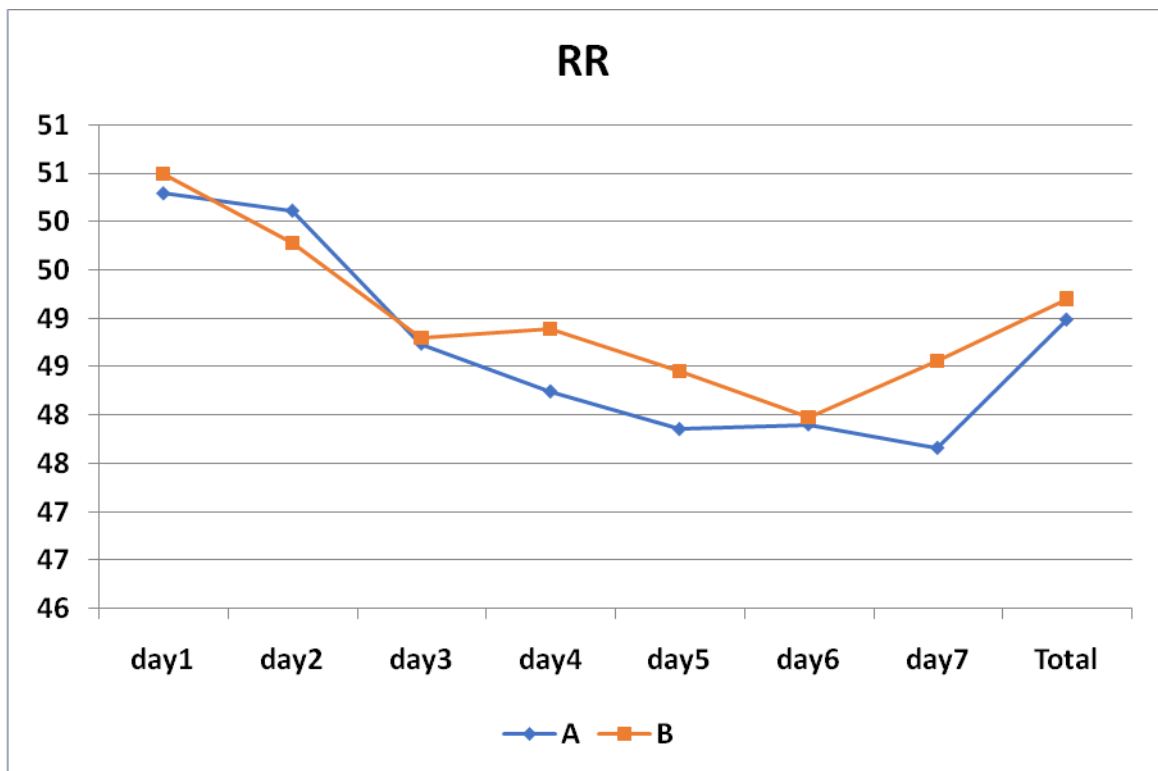


Figure E.5

Comparisons between the study groups for the HGB variable

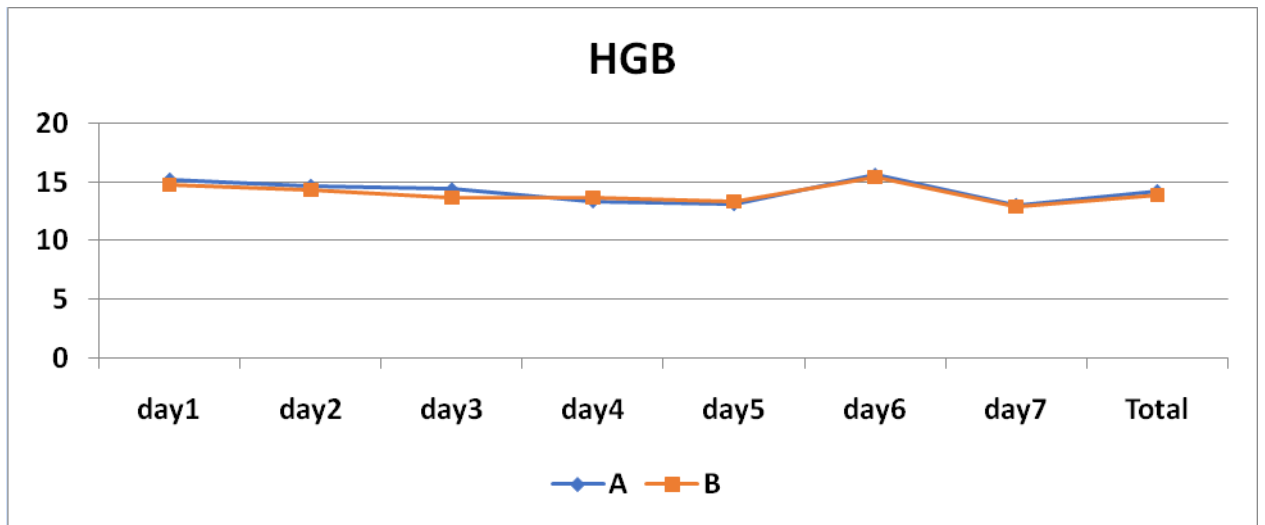


Figure E.6

Comparisons between the study groups for the PLT variable

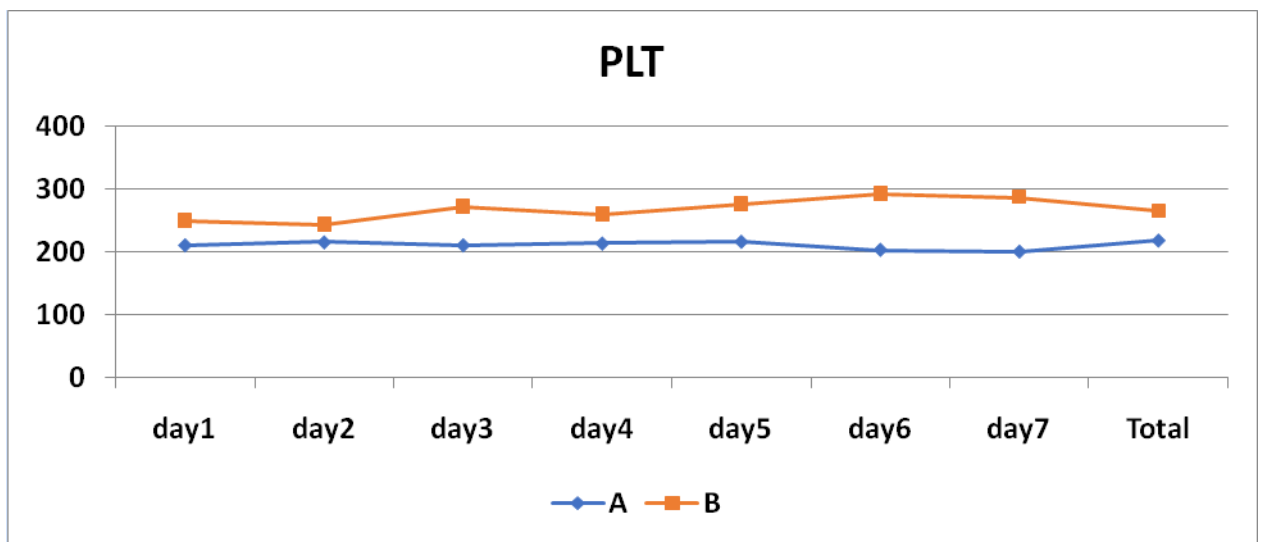


Figure E.7

Comparisons between the study groups for the BUN variable

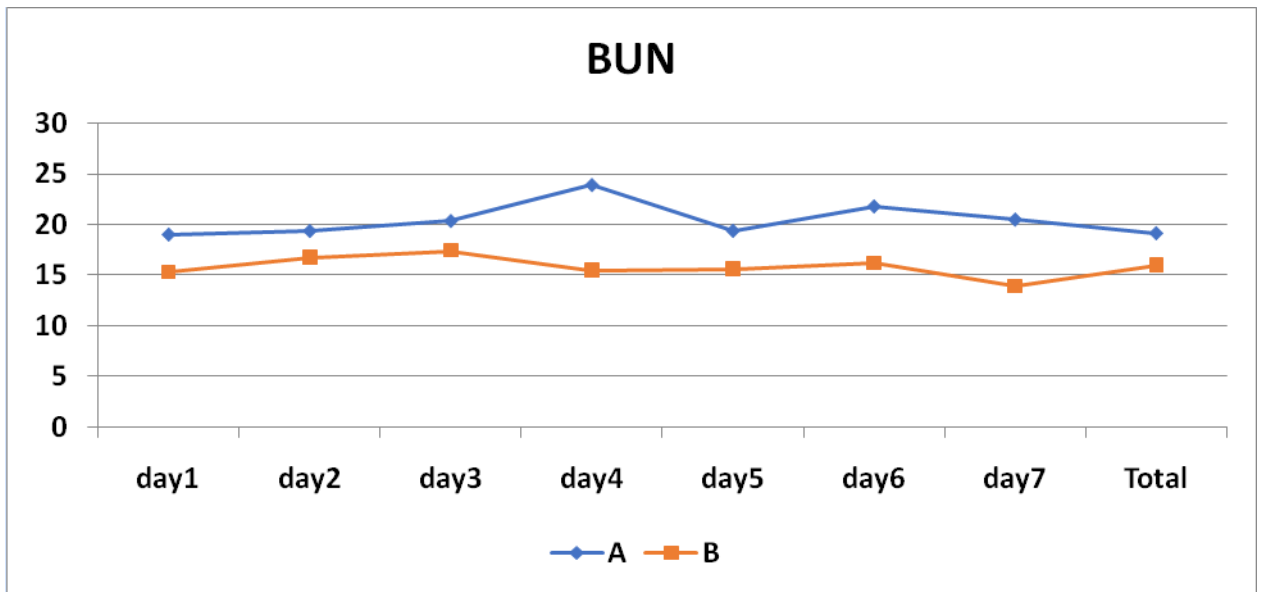


Figure E.8

Comparisons between the study groups for the CR variable

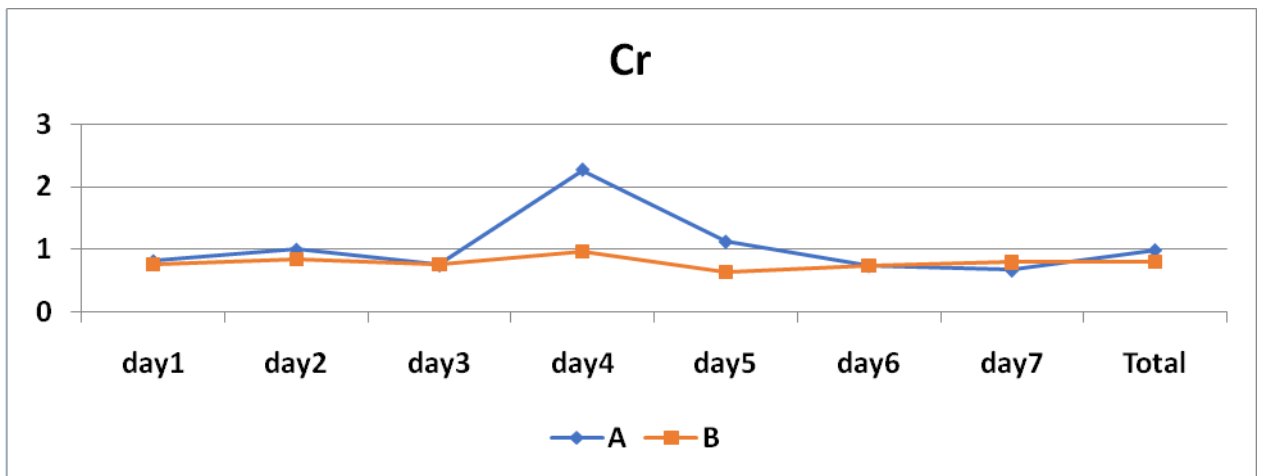


Figure E.9

Comparisons between the study groups for the ALBUMINE variable

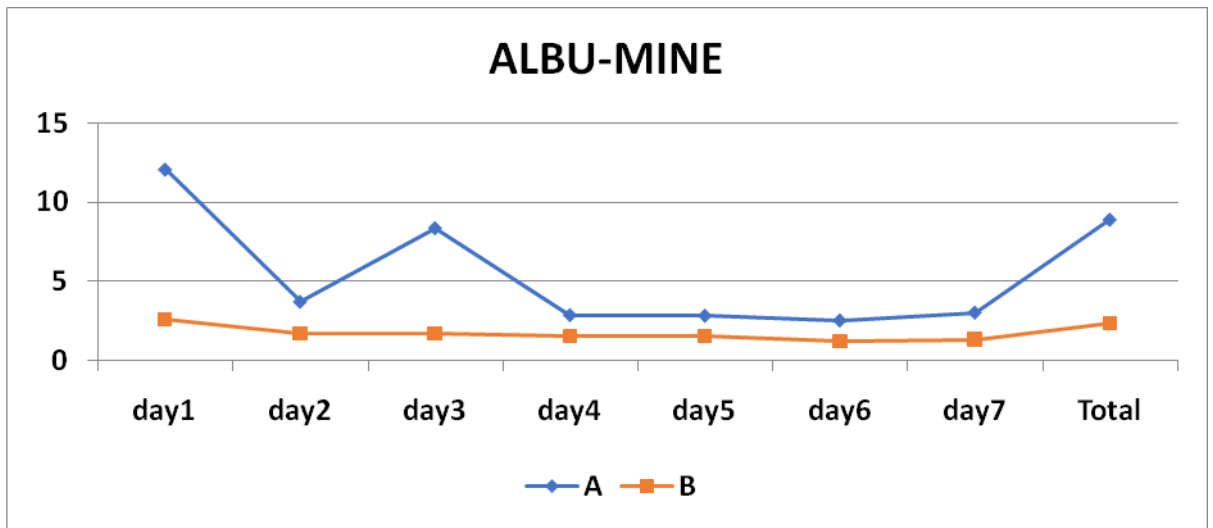


Figure E.10

Comparisons between the study groups for the CA variable

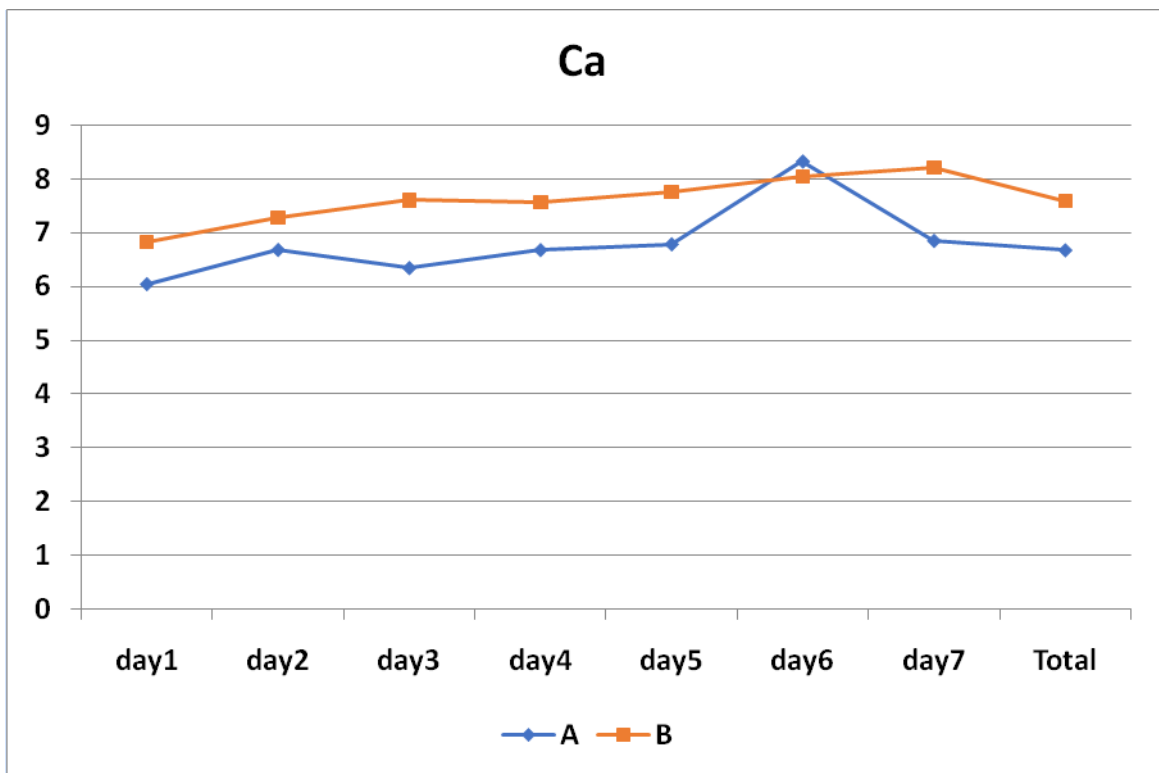


Figure E.11

Comparisons between the study groups for the GLUCOSE variable

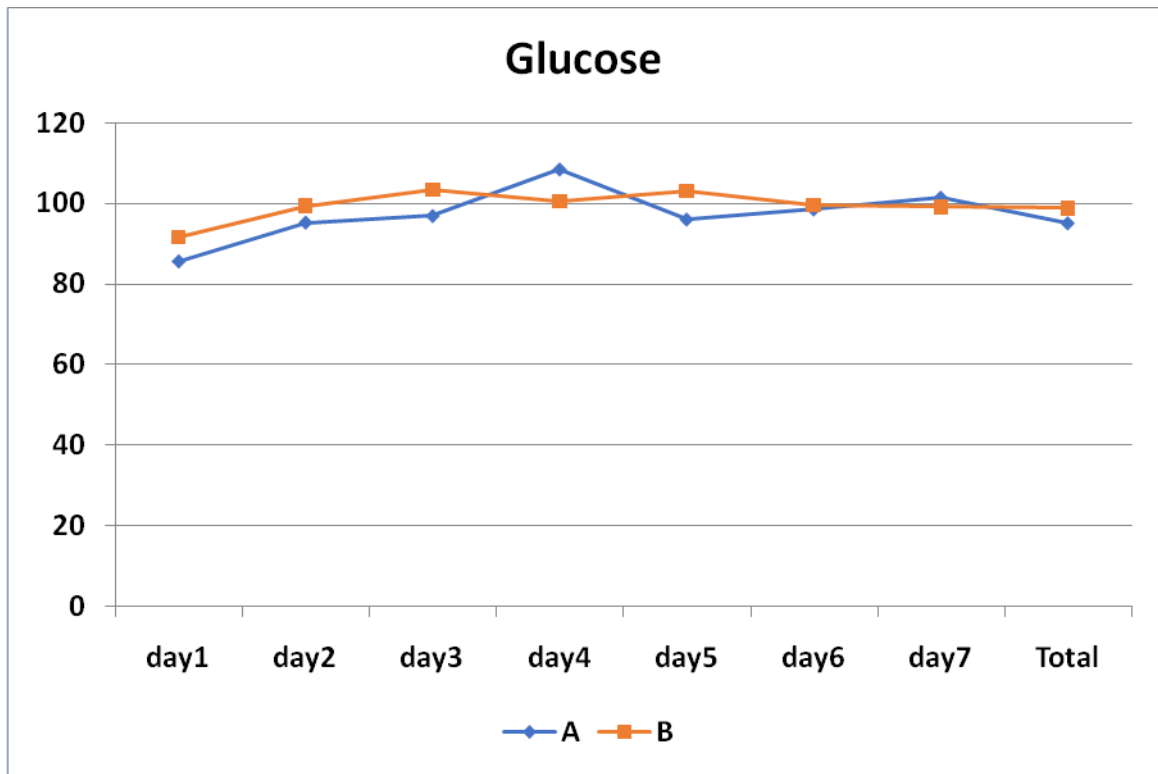


Figure E.12

Comparisons between the study groups for the BILIRUBIN variable

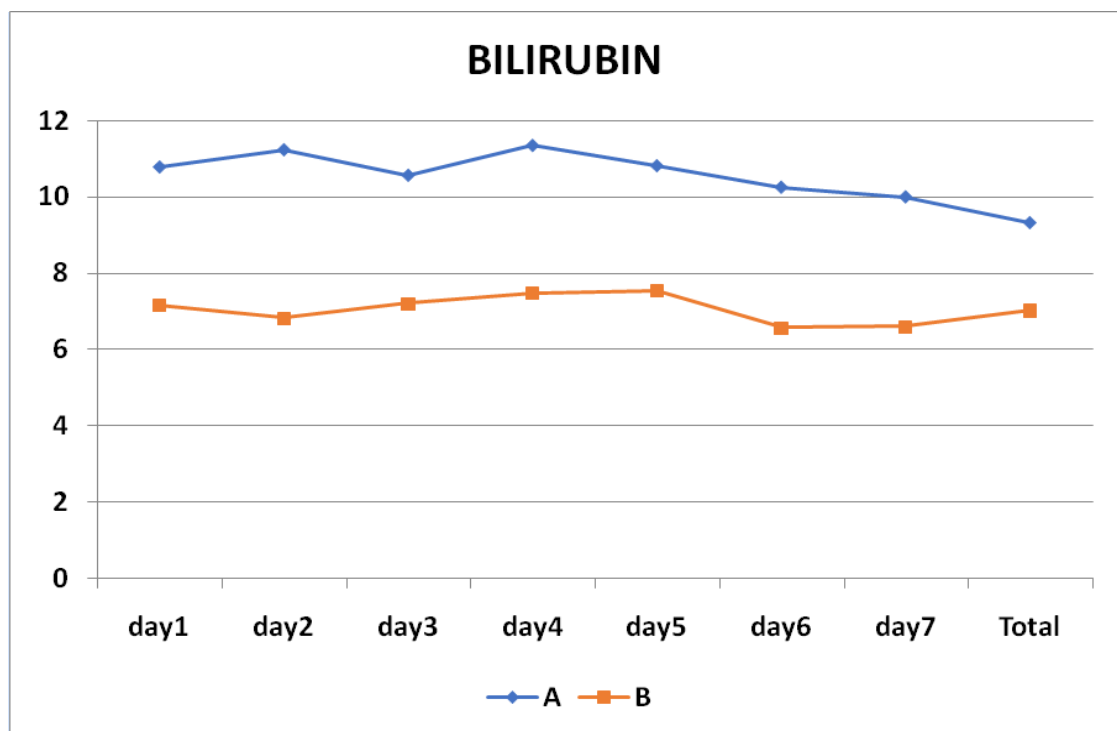
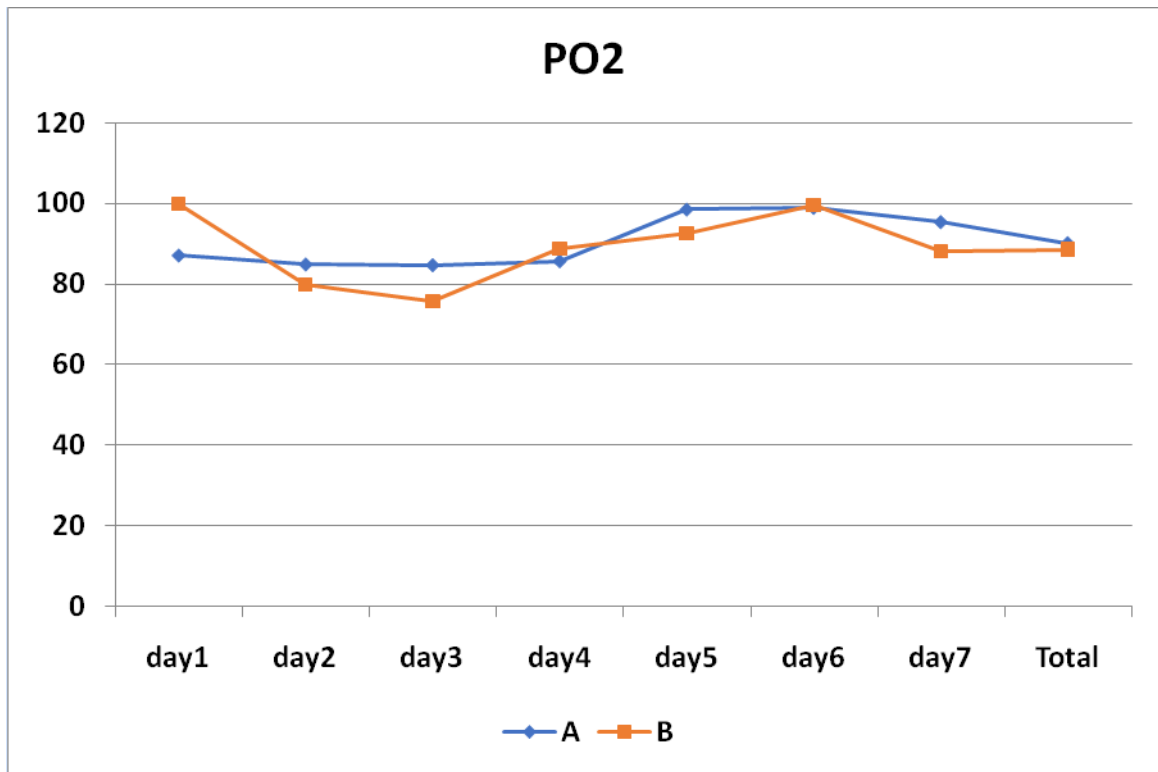


Figure E .13

Comparisons between the study groups for the PO2 variable



FigureE.14

Comparisons between the study groups for the TOTAL PEEP variable

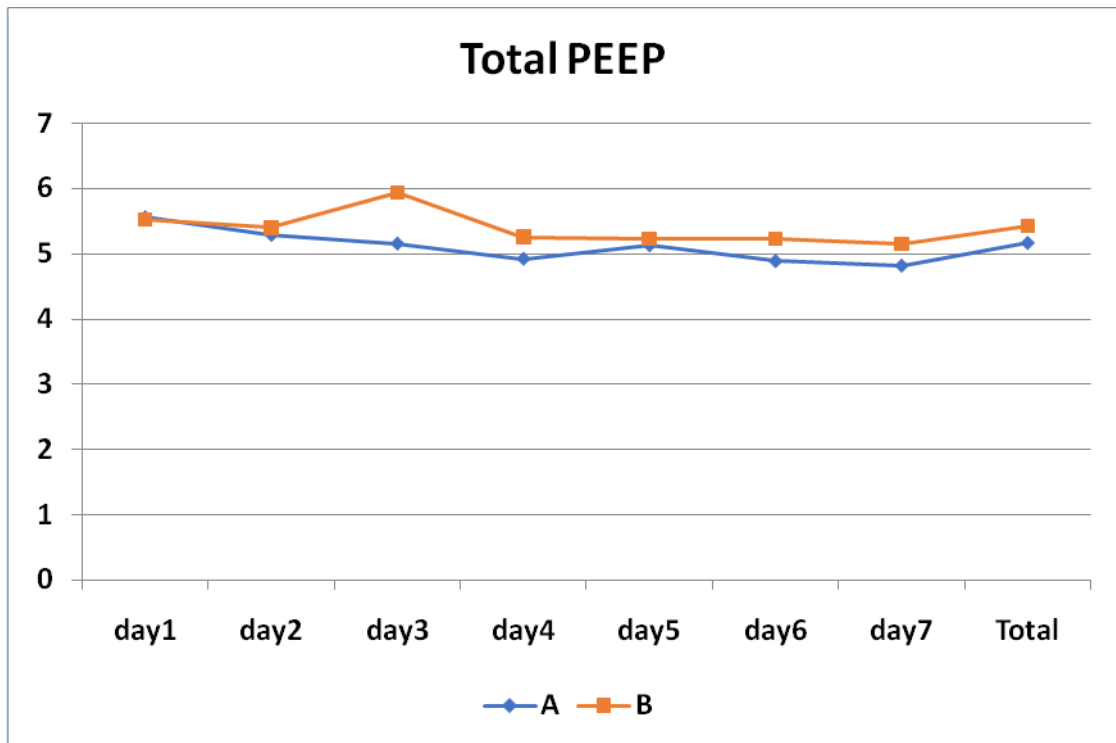


Figure E.15

Comparisons between the study groups for the WEIGHT variable

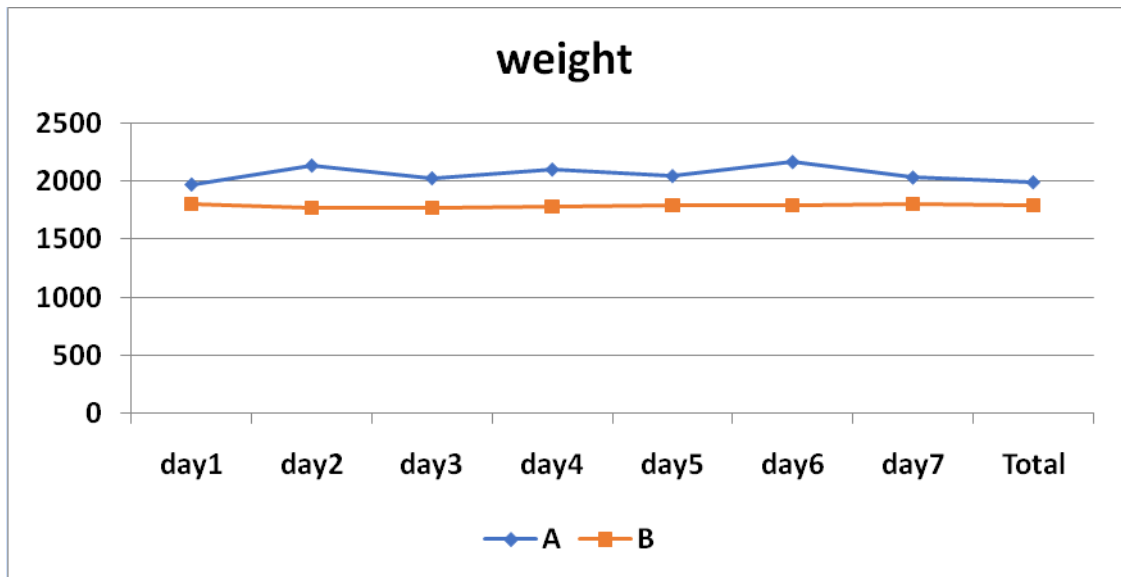
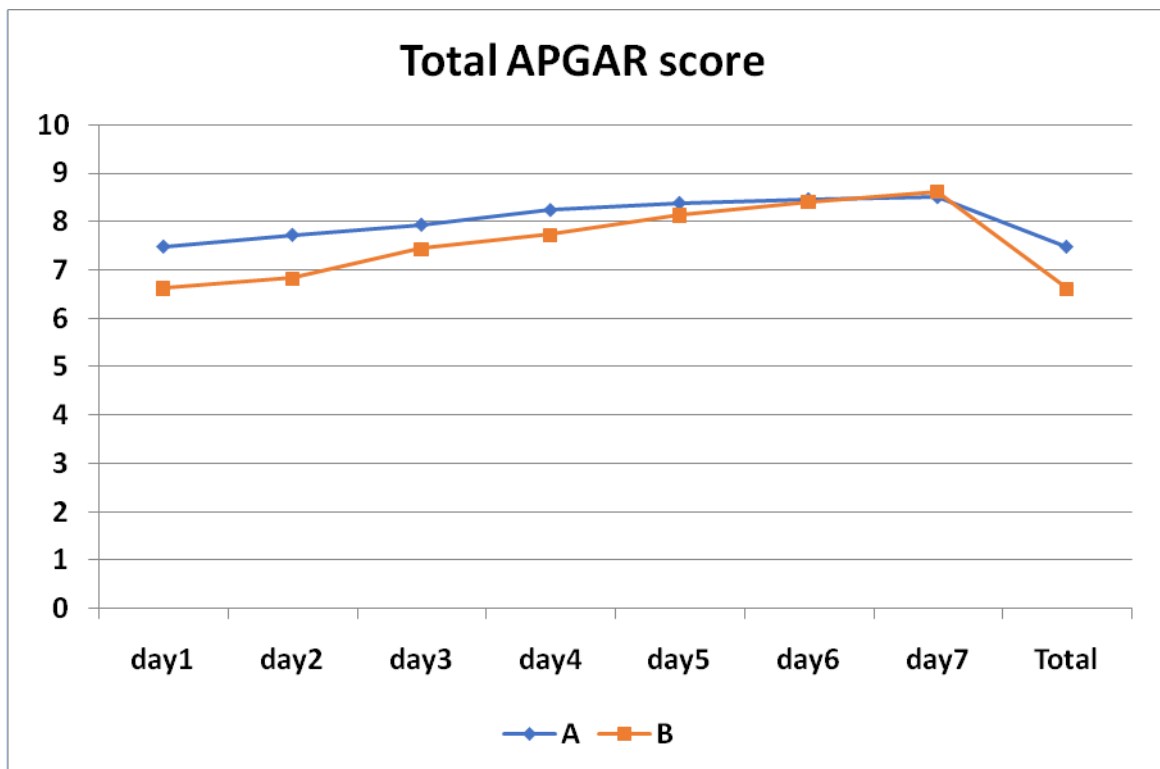


Figure E.16

Comparisons between the study groups for the Total APGAR score variable



Appendix F

information to apply for research data collection permission at the Palestinian Ministry of Health institutions

Research Title اسم البحث	The effectiveness of early enteral feeding protocol on preterm clinical outcomes in neonatal intensive care units in large hospital in Palestine. فعالية بروتوكول التغذية المعوية المبكرة على النتائج السريرية في وحدات العناية المركزة لحديثي الولادة في مستشفى كبير في فلسطين.
University Name اسم الجامعة	Al Najah National University
Principal Investigator/ Supervisor's name اسم الباحث/ المشرف	EmanAlshaweesh.Dr د. ايمان الشاويش
Students participating in the research أسماء الطلاب المشاركين في البحث	EshtyaqHamdan إشتياق حمدان
Specialty التخصص	Critical Care Nursing, Master Program
Abstract ملخص الدراسة	<p>Abstract:</p> <p>Background</p> <p>70% of preterm infants struggle with oral feeding due to poor motor maturity, neural pathways, respiratory and gastrointestinal system pathology, low tolerance for interaction, and unstable behavioral state organization. Preterm infant nutrition aims to meet normal growth rate and body composition.</p> <p>Method: The study employed a quazi experimental design comparing two groups of preterm infants: There were an intervention group, an experimental group (group E) who received an early enteral feeding protocol and the comparison group (group C) who did not receive this protocol, but received their regular routine care. Measures included demographic information and other factors with the infant, such as gestational age, birth weight, length of hospital stay and many others. Descriptive statistics, which included means, standard deviations and frequencies were employed while inferential techniques such as t-tests were used to compare group differences. This research was done among infants in the NICUs of Government Hospital and IBNSINA Hospital in Palestine during January-December 2023.</p> <p>Keywords: NICUs, Preterm Infants, low birth weight, Early</p>

enteral feeding, Late enteral feeding,

Brief Introduction:

Theoretical basis:

In preterm infants, early enteral feeding provides essential nutrients and encourages necessary growth. Although supplying these infants with sufficient total energy and protein may frequently take precedence, supplying them with sufficient micronutrients including 13 vitamins and a variety of minerals is still essential for fostering optimal physical growth and neurodevelopment. When compared to parenteral nutrition alone, early enteral feeding may significantly increase the overall supply of essential micronutrients through fortification or nutrient supplementation, particularly if parenteral additive shortages exist. In addition, preterm infants receiving total parenteral nutrition may not benefit sufficiently from parenteral micronutrient formulations. For example, joint guidelines for parenteral vitamin D administration range from 200–1000 International Units (IU) per day (or 80–400 IU/kg/day) (Bronsky et al., 2018; Thoene & Anderson-Berry, 2021).

A baby's birth weight of less than 2500 grams is considered to be low birth weight. Every year, more than 20 million babies are born with low birth weight (LBW), and more than 96% of these babies are born in developing nations (Cutland et al., 2017; Organization, 2011; Tewoldie et al., 2022). Preterm birth (birth before 37 weeks of gestation) or small size for gestational age (birth weight below 10th percentile) can result in LBW. Nutritional care for LBW infants, especially those with birth weights between 1000 and 2000 grams, is mostly either parenteral, enteral, or a combination of the two. The majority of developing nations, where resources are limited, provide a maintenance fluid consisting solely of glucose and electrolytes via intravenous fluid rather than parenteral nutrition (Bora & Murthy, 2017).

Enteral nutrition can be extremely vital supportive nutrition for neonates admitted to the intensive care units (Hay, 2018). However, the introduction of enteral feeding early after admission to the intensive care units remains highly controversial. While some healthcare practitioners suggest that enteral feeding should be delayed as it is expected to increase the demand of oxygen by

neonates, thus might deteriorate the hemodynamic instability of the neonates. Additionally, it is believed that early introduction of enteral feeding could be associated with higher risk for multiorgan dysfunction, small bowel necrosis,

	<p>necrotizing enterocolitis (NEC), and/or gastrointestinal ischemia(Dorling & Gale, 2019; Kalra et al., 2018). On the other hand, other practitioners believe that delayed enteral feeding can result in metabolic disorders, infections, and impairments to the functional adaptation of the neonatal gastrointestinal tract(Dorling & Gale, 2019; Hay, 2018; Kalra et al., 2018). Therefore, researchers and practitioners have suggested that early introduction of small volumes of enteral feeds (trophic feeding) might improve intestinal function, maturation, and thus may promote tolerance of enteral feeding. In today’s practice, neonates receive trophic enteral feeding as early as practically possible(Kalra et al., 2018).It is noteworthy mentioning that it is still unclear whether early or late enteral feeding can improve the energy balance among neonates.</p> <p>Problem Statement. Full-term and preterm neonates admitted to the neonatal intensive care units often require nutritional support. It has been demonstrated that inadequate nutrient intake, notably in the first postnatal week can be associated with poor growth and other significant clinical consequences in neonates with very low birth (Hay, 2018). Because of their prematurity after birth, a considerable percentage of neonates in the intensive care units are unable to tolerate oral and/or enteral feeding immediately. Therefore, neonates would often rely on parenteral nutrition for the few first weeks. During this period, partial enteral nutritional support might be provided to meet nutritional needs for adequate growth and maturity. This could also help avoid nutritional deficits in the first period and might help promote adequate growth.However, little studies have investigated the effects of early enteral feeding on clinical outcomes of full-term and preterm neonates admitted to the intensive care units. It is noteworthy mentioning that the metabolic pathways in neonates are still immature and the reservoirs of nutrients are limited. Additionally, the physiologic parameters in neonates are significantly different from those in older pediatric and adult populations (Chong et al., 2018). Moreover, neonates admitted to the intensive care units are highly vulnerable to malnutrition and poor growth (Hay, 2018; Pineda et al., 2018).</p>
<p>Methodology منهجية البحث</p>	<p>Methodology:</p> <p>Study Design:</p> <p>Study design: The study was a prospective, observation quasi experimental study design, in which two groups of preterm infants will be compared: an experimental group(group b) receiving early enteral feeding protocol , and a control group receiving routine care without the early enteral feeding protocol(group C).</p> <p>.</p> <p>Intervention: The experimental group will receive the early enteral feeding protocol, which involves enteral feedings</p>

within 24 hours of birth. The control group will receive routine care without the early feeding protocol. Both groups will receive the same type of formula, provided through nasogastric tube.

Study Population:

The study population will consist of preterm infants born between 28-36 weeks of gestation who are admitted to the NICU within the first 24 hours of life. Infants who meet the inclusion criteria was enrolled in the study. Infants with congenital anomalies or major illnesses that require surgery was excluded.

Site and setting

The study will be conducted in the neonatal intensive care units (NICUs) of two large hospitals in Palestine: Government Hospital and IBNSina Hospital in Jenin.

Study period

From January 2023 to dec 2023

Inclusion criteria

- 1) Gestational age (GA) greater than or equal less than 37 weeks
- 2) Birth weight less than 2500g capable of oral feeding
- 3) preterm intubated neonates or those on mechanical ventilation

Exclusion criteria

- 1) Congenital anomalies
- 2) Neurological impairment
- 3) Documented congenital or nosocomial sepsis
- 4) Requiring surgery

First group

The group of preterm infants on mechanical ventilator in the neonate intensive care unit in Ibsina hospital who will receive the early feeding protocol is a subgroup of the experimental group in the study on the effectiveness of early enteral feeding protocol on preterm clinical outcomes in neonatal intensive care units (NICUs) in large hospitals in Palestine

This subgroup will consist of preterm infants who are on mechanical ventilator and admitted to the neonatal intensive care unit in Ibsina hospital. These infants will be eligible for the study if they meet the inclusion criteria for the study, which could include being born between 30-37 weeks of gestation, being stable enough to receive enteral feedings, and being admitted to the NICU within the first 24 hours of life

The infants in this subgroup will receive enteral feedings

	<p>within 24 hours of birth, as part of the early enteral feeding protocol being studied. The outcomes of this subgroup will be compared to the outcomes of the control group to determine the effectiveness of the early enteral feeding protocol specifically in this subgroup of preterm infants on mechanical ventilator</p> <p>.</p> <p>Second group (routine care) A control group in a study is a group of participants who do not receive in Jenin hospital the experimental treatment or intervention being tested. In this case, the control group would be the group of participants who receive routine care but will not receive the early feeding protocol. This group is used as a comparison to see if the experimental treatment (early feeding protocol) has a significant effect on the outcome being studied.</p>
<p>Data collection methods and tools طرق جمع البيانات والأدوات</p>	<p>Data Collection : Data will be collected from medical records and direct observation of the infants. The following data will be collected: gestational age, birth weight, sex, Apgar score, length of mechanical ventilation, time to full enteral feedings, duration of hospital stay, and any adverse events. Data collection sheet, the researcher will develop a data collection sheet composed of 3 parts; Socio-demographic •</p> <p>Socio-demographic characteristics of neonates admitted in .3 NICU of Variables Categories Gestational age in week Birth weight in gram maternal age</p> <p>The study may collect data on the socio-demographic characteristics of neonates admitted to the neonatal intensive care units (NICUs) at Government Hospital and IbnSina hospital in Jenin, Palestine. The variables that may be collected include:</p> <p>Gestational age in weeks: This refers to the number of weeks a baby has been in the womb at the time of birth. It is used to classify premature neonates.</p> <p>Birth weight in grams: This refers to the weight of the baby at birth and can be used to classify low birth weight neonates.</p> <p>Maternal age: This refers to the age of the mother at the time of birth.</p> <p>2. The study may also collect data on the physical</p>

	<p>characteristics of the neonates admitted to the neonatal intensive care units (NICUs) at Government Hospital and IbnSina hospital in Jenin, Palestine. The variables that may be collected include:</p> <p>APGAR score: This is a quick assessment of a newborn's physical condition at the time of birth. It is used to identify newborns in need of immediate medical attention.</p> <p>Weight: This refers to the weight of the neonate.</p> <p>Height: This refers to the length or height of the neonate.</p> <p>Head circumference: This refers to the measurement of the circumference of the head of the neonate.</p> <p>APGAR score, weight, height, and head circumference are usually measured at the time of birth, and then on day 7 or until discharge from the ICU.</p> <p>These variables can be used to evaluate the physical growth and development of the neonates in the study. The specific measurement techniques and units of measurement will depend on the study's design and protocol.</p>
<p>Dates and time of data collection تواريخ وقت جمع البيانات</p>	<p>Data will be conveyed during July/2023-Dec/2023.</p>
<p>Sample size حجم العينة</p>	<p>Pocock's sample size formula is used to calculate the required sample size for comparing proportions of a specific outcome in two equally sized groups. The formula takes into account the estimated proportions of the outcome in each group, the level of statistical significance, and the desired power..the sample size for this study will be determined based on power analysis using the following assumptions: $\alpha=0.05$, $\beta=0.2$, power=0.8, and an effect size of 0.5. The estimated sample size required for this study is 80 infants, with 40 in the experimental group and 40 in the control group.</p>
<p>Who will collect data or samples من سيجمع البيانات أو العينات</p>	<p>EshtyaqHamdan</p>
<p>Questionnaire or questions of the interview (copy) استبيان أو أسئلة المقابلة (نسخة)</p>	<p>Appendix2</p>

Ethical considerations الاعتبارات الاخلاقية	This study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Informed consent will be obtained from the parents of each infant enrolled in the study. The study protocol will be reviewed and approved by the institutional review board (IRB) of An-Najah National University, as well as the scientific research bodies of the two hospitals.
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جامعة النجاح الوطنية

كلية الدراسات العليا

فعالية بروتوكول التغذية المعوية المبكرة على النتائج السريرية في
وحدات العناية المركزة لحديثي الولادة في اثنين من المستشفيات الكبيرة
في جنين

اعداد

إشتياق حاتم صالح حمدان

اشراف

د. ايمان الشاويش

قدمت هذه الرسالة استكمالاً لمتطلبات الحصول على درجة الماجستير في تمريض العناية المكثفة، من كلية الدراسات العليا، في جامعة النجاح الوطنية، نابلس - فلسطين.

2024

فعالية بروتوكول التغذية المعوية المبكرة على النتائج السريرية في وحدات العناية المركزة لحديثي الولادة في اثنين من المستشفيات الكبيرة في جنين

اعداد

اشتياق حاتم صالح حمدان

إشراف

د. ايمان الشاويش

الملخص

الخلفية: يعاني حوالي 70% من الأطفال الخدج من صعوبة التغذية عن طريق الفم بسبب ضعف النضج الحركي والمسارات العصبية وأمراض الجهاز التنفسي والجهاز الهضمي وانخفاض تحمل التفاعل وتنظيم الحالة السلوكية غير المستقرة.

الأهداف: تهدف الدراسة إلى تقييم النتائج السريرية للأطفال الخدج الذين يتلقون بروتوكولات التغذية المعوية المبكرة مقارنة بأولئك الذين يتلقون بروتوكولات التغذية المعوية القياسية في وحدات العناية المركزة لحديثي الولادة.

المنهجية: استخدمت الدراسة تصميمًا شبه تجريبي يقارن بين مجموعتين من 45 طفلًا خديجًا في كل مجموعة. كانت هناك مجموعة تدخل ومجموعة تحكم (المجموعة ج) لم تتلق بروتوكول التغذية المعوية المبكرة ومجموعة تجريبية (المجموعة هـ) تلقت بروتوكول التغذية المعوية المبكرة. النتائج: تظهر النتائج فرقًا كبيرًا عند مستوى 0.05 بين مجموعتي الدراسة (ج و هـ) في زيادة الوزن فقط في اليوم الأول والسادس. بالنسبة للعلامات الحيوية ضمن المعدل الطبيعي لكل مجموعة، كان لدى المجموعة (ج) معدل ضربات قلب أعلى في أيام مختارة وفي المجموع مقارنة بالمجموعة (هـ) بالنسبة للقيم المعملية، كان لدى المجموعة جنسبة أعلى من خلايا الدم البيضاء، والنيتروجين اليوريا، والصوديوم، والبوتاسيوم، والألبومين

(في اليوم الخامس فقط)، والبيليروبين مقارنة بالمجموعة (هـ)، والتي تقع ضمن النطاق الطبيعي لهذه المتغيرات، وكان لدى المجموعة جنسية أقل من Ca وPLT مقارنة بالمجموعة (هـ)، مع عدم وجود اختلافات كبيرة في HGB وCR والجلوكوز. عند إعداد جهاز التنفس الصناعي، كان إجمالي FiO2 لمدة 7 أيام في المجموعة أعلى منه في المجموعة (هـ)، وكان المعدل المحدد في المجموعة أعلى منه في المجموعة (هـ). لذلك، كانت نسبة الأطفال الذين تم إخراجهم من الأنبوب بشكل أسرع في المجموعة (هـ) أعلى منها في المجموعة (ج)، مما يشير إلى أن نسبة إقامتهم في المستشفى للمجموعة (هـ) كانت أقل من المجموعة (ج) عن طريق تقليل نسبة الأكسجين إليهم بشكل أسرع.

الخلاصة: قد يؤدي تنفيذ بروتوكولات التغذية المعوية المبكرة إلى تحسين النتائج، والاستقرار السريري عند الأطفال الخدج، وتقليل مدة إقامتهم في المستشفى، مما يساهم في تحسين النتائج الصحية العامة خلال فترة حديثي الولادة.

الكلمات المفتاحية: وحدات العناية المركزة لحديثي الولادة، الأطفال الخدج، انخفاض الوزن عند الولادة، التغذية المعوية المبكرة، التغذية المعوية المتأخرة.