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Research Protocol

Paediatrics Section

Efficacy of Pasteurised Donor Human Milk on the Growth of Preterm Neonates: A Research Protocol of a Randomised Control Trial

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ABSTRACT

Introduction: Growth restriction is a common complication affecting a significant proportion of Very Low Birth Weight (VLBW) infants, with estimates suggesting that up to 97% of these vulnerable newborns are impacted. While Maternal Own Milk (MOM) is the gold standard for nutrition, pasteurised Donor Human Milk (DHM) offers a safe and nutritious alternative when MOM is not available. This research investigation aims to examine and compare the effects of MOM and DHM on growth parameters and outcomes in preterm infants.

Need of the study: Preterm infants are disproportionately vulnerable to neurodevelopmental delays and other complications, underscoring the importance of identifying effective interventions to support their growth and development. While MOM is widely recognised as the optimal source of nutrition, the potential benefits of DHM warrant further investigation. Given the limited research directly comparing MOM and DHM, this study aims to address this knowledge gap and explore the impact of these nutritional sources on the developmental outcomes of preterm neonates.

Aim: To compare the efficacy of pasteurised DHM on anthropometric indices (Weight/Head circumference/Length) of preterm neonates until the age of discharge.

Materials and Methods: This randomised controlled trial will be conducted in the Neonatal Intensive Care Unit (NICU) and Ward of Jawaharlal Nehru Medical College and AVBRH Hospital, Sawangi, Wardha, Maharashtra, India, from January 2024 to January 2026. All preterm infants born before 37 weeks of gestation and receiving enteral nutrition during the study duration will be enrolled. Participants will be randomly assigned to one of three groups based on the type of milk consumed: MOM, DHM, or a combination of both.

Anthropometric measurements {Weight (once every day in the morning from 6 AM to 8 AM), head circumference and length (both once weekly on every Sunday in the morning from 6 AM to 8 AM)} will be recorded regularly until discharge. Recording anthropometric measurements regularly (daily/weekly) at consistent times (6 AM-8 AM) enables timely detection of growth issues, prompt intervention and informed discharge planning. This approach ensures accuracy, consistency and comprehensive tracking of patient growth and development until discharge. Data analysis will be performed using Statistical Package for the Social Sciences (SPSS) version 21.0 software. Analysis of Covariance (ANCOVA) will be employed to compare anthropometric indices among groups. Weight Gain Velocity (WGV) will be calculated by dividing the weight on the 10th day by the weight on the 1st day, multiplying by 1,000 and expressing the result in grams per kilogram per day (g/kg/day). Logistic regression analysis will be used to compare the incidence of Feeding Intolerance (FI) among groups.

Keywords: Anthropometric indices, Extrauterine growth retardation, Neonatal intensive care unit, Preterm neonates

INTRODUCTION

Postnatal growth restriction, affecting up to 97% of VLBW infants, is a pervasive concern in neonatal care. This phenomenon, known as Extrauterine Growth Restriction (EUGR), is linked to unfavourable long-term outcomes. MOM is the preferred source of nutrition for all newborns, including preterm infants. However, when MOM is scarce or unavailable, pasteurised DHM provides a safe and nutritious alternative and is considered the next best option. As advances in neonatal care improve survival rates for preterm infants, attention is shifting towards optimising nutritional management to enhance the quality of survival [1].

The advantages of human milk for full-term infants are well established and recent research indicates that preterm infants may derive even greater benefits from human milk [2]. Breast milk offers numerous benefits for infants, including physical, economic, convenience, physiological, biochemical, microbiological, non allergic, immunological, psychological, maternal and epidemiological advantages. These benefits encompass optimal nutrition, cost-effectiveness, ease of use and enhanced immune defense, ultimately decreasing morbidity and mortality [2,3]. Breastfed babies are 14 times less likely to die from diarrhoea and four times less likely to die from respiratory diseases [2]. Overall, breast milk provides a comprehensive package of benefits, making it the ideal choice for infant nutrition and development.

However, some mothers are unable or unwilling to provide breast milk for their babies. In such cases, pasteurised DHM offers a suitable alternative, retaining many of the bioactive components and benefits of human milk while minimising the risk of infectious agent transmission. Although pasteurisation may affect certain nutritional and immunological properties of human milk, numerous immunoglobulins, enzymes, hormones and growth factors remain intact or are only slightly diminished [4].

The nutritional profile of human milk undergoes changes throughout the lactation period and is also influenced by the pasteurisation process. Consequently, when relying on DM as a long-term nutrition source, it is essential to acknowledge and account for the notable differences in nutritional content between MOM and pasteurised DM [5].

Human milk donated by mothers who have given birth to preterm infants has distinct nutritional properties, with notably higher levels of protein, sodium and chloride compared to milk from mothers who have delivered term infants. This unique composition makes it particularly well-suited for the nutritional needs of preterm babies [5].

This study will investigate the comparative effects of MOM and DHM on growth parameters, sepsis incidence, Necrotising Enterocolitis (NEC) and FI in preterm infants. Preterm neonates are

disproportionately vulnerable to neurodevelopmental delays and other complications, making interventions that enhance their growth and developmental potential particularly valuable [6].

Despite extensive research comparing the effects of MOM and infant formula, as well as Donor Milk (DM) and infant formula, a significant knowledge gap exists regarding the direct comparison between MOM and DM. This study aims to bridge this gap by investigating the impact of MOM and pasteurised DM on growth parameters and select outcomes in preterm infants.

The aim of the study is to investigate the effects of MOM and pasteurised DHM on growth parameters and selected outcomes in preterm infants.

Objectives

Primary objective

- To record and track daily weight, as well as weekly head circumference and length measurements for preterm babies in the study cohort until their discharge from the hospital.
- To compare the anthropometric indices (weight, head circumference and length) in babies who are receiving their NEC, DHM, or both.

Secondary objective: To compare the morbidities and mortality in all the groups.

Hypothesis

Null hypothesis (H0): The improved postnatal growth and weight gain will not be the same when using MOM, pasteurised DHM, or a combination of both.

Alternative hypothesis (H1): Any form of human milk, whether MOM or pasteurised DHM, is associated with improved postnatal growth and weight gain. This effect is observed for both types of milk, whether used separately or together.

REVIEW OF LITERATURE

Every infant deserves optimal nutrition from the outset, ideally through breastfeeding or receipt of donated human milk. Human breast milk is widely recognised as the most nutritious and healthy choice for babies. Research has consistently shown that breast milk and DHM are the preferred nutritional sources for fragile and vulnerable infants in the NICU [7].

Montjaux-Régis N et al., conducted a comparative study on the effects of varying proportions of MOM on infant growth. Their analysis revealed that infants receiving higher percentages of MOM gained more weight than those fed DM, although linear growth rates were similar across the three groups [8]. According to the World Health Organisation (WHO), donated milk is the next best alternative to MOM for infants who cannot be breastfed [9].

However, the pasteurisation process and storage of DM can lead to a loss of micronutrients and anti-infective properties, making it not entirely equivalent to fresh mother's milk [10]. Nevertheless, donated breast milk retains sufficient bioactivity and immunological properties to make it a superior choice compared to formula feeds.

The macronutrient and mineral content of DM lacks standardisation due to natural biological variability. Although pasteurisation has a minimal impact on certain nutritional components, such as carbohydrates, fats, fat-soluble vitamins and salts, protein content is more susceptible to denaturation, with approximately 13% affected by heat [10]. Research has demonstrated effective pasteurisation methods that preserve essential nutrients. For instance, Czank C et al., found that pasteurising human milk at 57°C for 30 minutes retains at least 90% of secretory IgA, lactoferrin and lysozyme while eliminating 99.9% of tested bacterial species [11]. Additionally, Baro C et al., showed that high-temperature short-time pasteurisation (72°C for 15 minutes) preserves higher levels of IgA, lactoferrin and bile salt-dependent lipase compared to standard methods [12]. Notably, the variability in protein and fat content is reduced in DM due to the pooling process [13]. The composition of of pasteurised Donor Milk (DM) has been presented in [Table Fig-1] [14].

Component	Retention
Immune components	
C3	0
Immunoglobulin A (IgA)	0-150%
Immunoglobulin G (IgG)	0-82.8%
Immunoglobulin M (IgM)	0
Lactoferrin	0-123%
Lysozyme	0-393%
Enzymes, Growth factor	
Alpha 1-antitrypsin	61.8%
Lipoprotein lipase	Completely destroyed
Bile salt stimulated lipase	Completely destroyed
Esterase	Completely destroyed
Transforming growth factor (alpha)	93.9%
Transforming growth factor (beta)	99%
Whey: casein	Whey reduced relative to fat

[Table/Fig-1]: Composition of pasteurised Donor Milk (DM) [14]. Groups based on milk intake.

The pasteurisation of DM may compromise its protective effects due to thermal treatment, potentially reducing anti-infective components, growth factors and nutrients [15]. However, research shows that pasteurised DM still offers benefits. A study by Narayanan I et al., found that pasteurised DM retained some protective effects, with a lower incidence of infection (10.5%) compared to formula feeds (33.3%) [13]. Additionally, a meta-analysis by Boyd CA et al., revealed that an exclusive diet of DM reduced the risk of NEC by 79% [16]. Furthermore, Schanler RJ et al., reported comparable weight gain rates between fortified DM (17.1 g/kg/d) and MOM (18.8 g/kg/d) [17]. Williamson S et al., noted that raw human milk offers better nitrogen retention and fat absorption than pasteurised milk, with fat absorption reduced to 72.9% due to pasteurisation [18].

The concept of human milk banking dates back to 1909, when the first milk bank was established in Vienna, Austria. Prior to this, wet nursing was a common practice, but concerns about the health and lifestyle of wet nurses, as well as the risk of transmitting infections through milk, led to the development of human milk banking. The first milk bank in the United States was launched at the Boston Floating Hospital and since then, numerous milk banks have been established worldwide. In Asia, the first milk bank was set up at the Lokmanya Tilak Municipal General Hospital in Mumbai, India, in 1989. Globally, there is a growing interest in milk banking, driven in part by recommendations from prominent pediatric societies, including the Academy of Breastfeeding Medicine (ABM), the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the American Academy of Paediatrics (AAP). These organisations advocate for human milk feeding in premature infants, with breastfeeding being the first choice and DM being the next best alternative. As a result, there is a surge in efforts to establish milk banks in India and other Asian countries, aiming to provide a safe and reliable source of human milk for vulnerable infants [19].

MATERIALS AND METHODS

This randomised controlled trial, which involves single blinding (outcome assessor blinding), will be conducted in the NICU Department of Neonatal Intensive Care Unit (NICU) and Ward of Jawaharlal Nehru Medical College and AVBRH Hospital, Sawangi, Wardha, Maharashtra, India. Data collection will take place from January 2024 to January 2026. Ethical approval for the study protocol has been obtained from the Institutional Ethical

Committee (IEC) prior to the commencement of the study, with registration number Datta Meghe Institute of Higher Education and Research (DMIHER) (DU)/IEC/2023/09. The trial has been registered on the Clinical Trials Registry- India (CTRI) website with reference number CTRI/2024/04/065657. All preterm infants born before 37 weeks of gestation and receiving enteral nutrition during the study period will be enrolled.

Inclusion criteria: Preterm neonates (<37 weeks gestation) on enteral feeding admitted to the NICU/ward until discharge.

Exclusion criteria:

- Preterm neonates with any major anomalies, gastrointestinal anomalies, limb malformations, multiple malformations, chromosomal anomalies, heart malformations, syndromic conditions, or congenital anomalies such as Tracheoesophageal Fistula (TEF), Congenital Diaphragmatic Hernia (CDH), intestinal obstruction, etc.
- Preterm neonates who have not been fed orally for one week or more, such as those with NEC.
- Preterm neonates suspected of having severe metabolic disorders involving proteins or carbohydrates (where milk feeds are contraindicated).
- Preterm neonates receiving total or partial parenteral nutrition.
- Preterm neonates with hydrocephalus, regarding head circumference outcomes.

Study Procedure

All preterm infants born before 37 weeks of gestation and receiving enteral nutrition during the study duration will be enrolled and will be assigned to one of three groups based on milk intake depending on if the mother of a premature infant does not produce sufficient breast milk.

Following informed consent from parents, preterm neonates will be enrolled in this single-centre, computer-generated randomised controlled trial. The study aims to compare outcomes between preterm infants receiving predominantly MOM, those fed exclusively with pasteurised DM and those receiving a combination of both (DM+MOM). Preterm neonates born at less than 37 weeks and admitted to the NICU or ward will be assigned to one of three groups based on their milk intake, as summarised in [Table/Fig-2].

Group MOM	Group DM	Group (DM+MOM)
Preterm infants receiving predominantly Mother's Own Milk (MOM)	Those fed exclusively pasteurised Donor Milk (DM)	Those receiving a combination of both (DM+MOM).

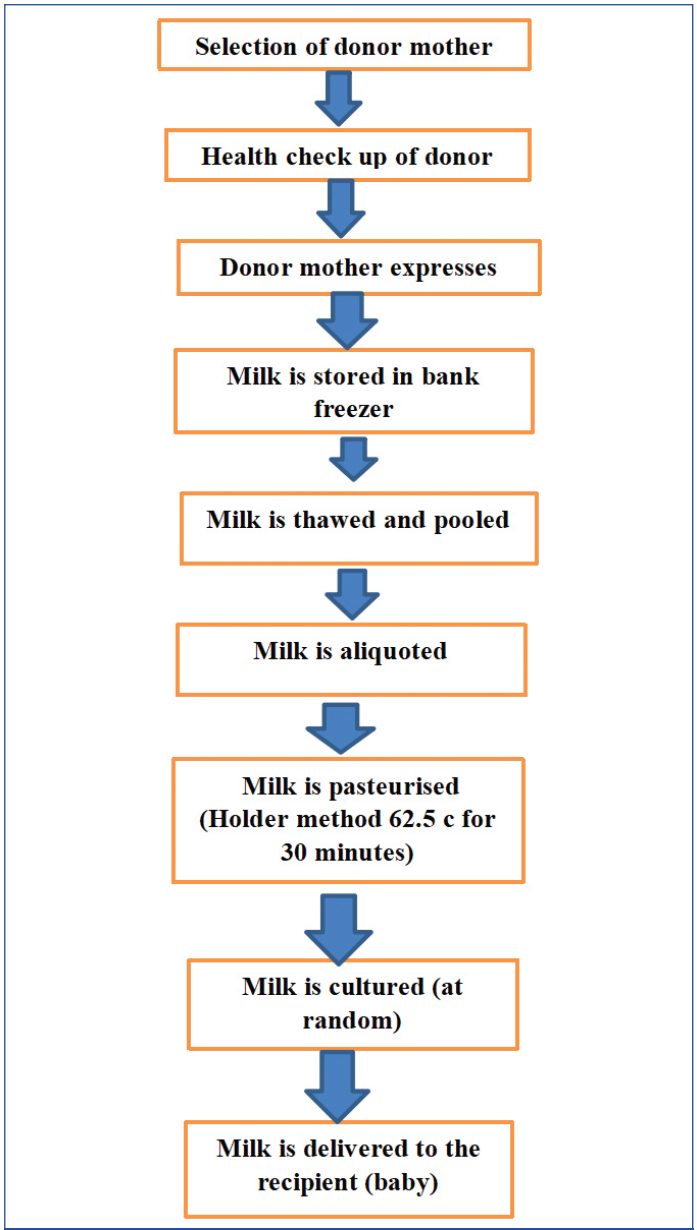
[Table/Fig-2]: Groups based on milk intake.

The human milk banking process for procuring donated milk is described as follows [Table/Fig-3] [20].

Human milk fortification: Fortifying expressed breast milk or human DM increases the nutrient content of the milk without compromising its other beneficial effects.

The authors will add Lactodex HMF (1 g/sachet) to 25 mL of human milk. Lactodex HMF (1 g/sachet) contains whey protein (0.27 g), vitamin D (3.32 mg), vitamin A (60 mcg), calcium (15.80 mg), zinc (40 mcg), iron (0.30 mg, fortified) and 100% maltodextrin (MCT). It also includes vitamin B1, vitamin B2, vitamin B3 (nicotinamide), vitamin B5 (pantothenic acid), vitamin B6, vitamin B12, vitamin C, vitamin E, vitamin K, iron, folic acid, biotin, chloride, potassium, phosphorus, sodium, magnesium, copper and manganese. Data will be collected through daily weight measurements using an electronic scale (ACU-CHECK TS500 Digital Weighing Machine) at a consistent time as described below.

The neonatal growth and development records comprise the following parameters:



[Table/Fig-3]: Human milk banking process [20].

- **Days to regain birth weight [21]:** The number of days taken by the infant to return to their birth weight.
- **Rate of gain in weight [22]:** Average daily or weekly weight gain (g/kg/day or g/day).
- **Length [23]:** The neonate's length will be measured using an infantometer (Standard steel, 1NO1).
- **Head circumference [23]:** Occipitofrontal Circumference (OFC) will be measured using a non stretchable plastic measuring tape (Ibis medical neonatal head circumference tape, PVC).
- **Time to achieve full feed [24]:** The number of days taken to transition from partial to full feeding.
- **Incidence of NEC [24]:** Presence or absence of NEC, a serious gastrointestinal condition common in preterm infants.

The other parameters analysed comprise:

- **Human Milk Fortifier (HMF):**
  - Initiation date
  - Quantity (volume/day)
- **Feed intolerance episodes:**
  - Frequency (number/day)
  - Severity (mild, moderate, severe)
- **Daily skin-to-skin contact hours:**
  - Duration (hours/day)

Anthropometric measurements, including weight (taken once every day in the morning from 6 AM to 8 AM), head circumference and length (both taken once weekly every Sunday in the morning from 6 AM to 8 AM), will be plotted on Modified Fenton's (2013) intrauterine chart [25,26]. Follow-up will continue until discharge, with documentation of discharge weight, length, head circumference and hospital stay outcome.

Anthropometric measurements are taken at consistent times (6 AM-8 AM) because morning rounds start at 9 AM every day. The NICU protocol recommends that the weight of every baby be recorded during this time by the nursing staff. Single-blinding is employed to reduce potential bias in outcome assessment, ensuring that the assistant researcher collecting and recording data is unaware of the group assignments.

This study will provide valuable insights into the effects of different milk feeding regimens on preterm neonate outcomes, including growth, development and morbidity. By comparing the outcomes of preterm infants receiving MOM, DHM, or a combination of both, this study aims to inform evidence-based practice and improve the care of preterm neonates.

Feeding protocols [Table/Fig-4] [27]: Eligible neonates will undergo daily assessments for feed initiation, ensuring haemodynamic stability, a soft abdomen, meconium passage and the absence of abdominal distension. Once these criteria are met, feeds will be initiated as intermittent boluses at 2-hour intervals, following a standardised protocol across all three groups. Daily fluid and milk requirements will be determined based on the neonate's day of life, weight changes and associated co-morbidities, such as patent ductus arteriosus and urine output. Feeds will be advanced until the infant reaches a target volume of 180-200 mL/kg/day. Upon transitioning from gavage feeds to direct feeds, infants will be fed ad libitum. MOM will be strongly recommended for all neonates, with efforts made to procure MOM for each infant. Mothers will be counselled by lactation consultants, resident doctors and nursing staff to express breast milk within 6 hours of delivery, followed by 2-3 times a day. A human milk fortifier (containing 0.27 g protein, 0.04 g total fat and 0.49 g carbohydrates per 1g powder sachet) will be added to expressed breast milk (1 sachet per 25 mL) once the infant reaches 100 mL/kg/day of enteral feeds. Caffeine and other nutritional supplements will be administered according to the unit's standard policy across all three groups.

Gestational age and weight	Starting volume	Increment
32 to 37 weeks and more or birth weight >1.250 kg	Full feeds	As per days requirement
30 to 32 weeks or birth weight between 1 kg and 1.25 kg	30 mL/kg	30 mL/kg
28 to 30 weeks or birth weight 750 to 1 kg	20 mL/kg	20 mL/kg
<28 weeks or birth weight <750 grams	10 mL/kg	10 mL/kg×2 days Increased by 10 mL/kg Increased by 20 mL/kg once the neonate is tolerating feed of 60 to 80 mL/kg

[Table/Fig-4]: Feeding protocol flowchart [27].

Sample size calculation:

$n_1=((Z(\alpha/2)+Z(\beta))^2 * (\sigma_1^2+\sigma_2^2))/(m_1-m_2)^2$

Estimated sample size for two sample comparison of means [28].

Test Ho: $m_1=m_2$, where m1 is the mean in population 1 and m2 is the mean in population 2

Alpha=5% (two-sided)

power=90%

m1=8.2

m2=1-5

sd1=9.5

sd2=7.6

n2/n1=1

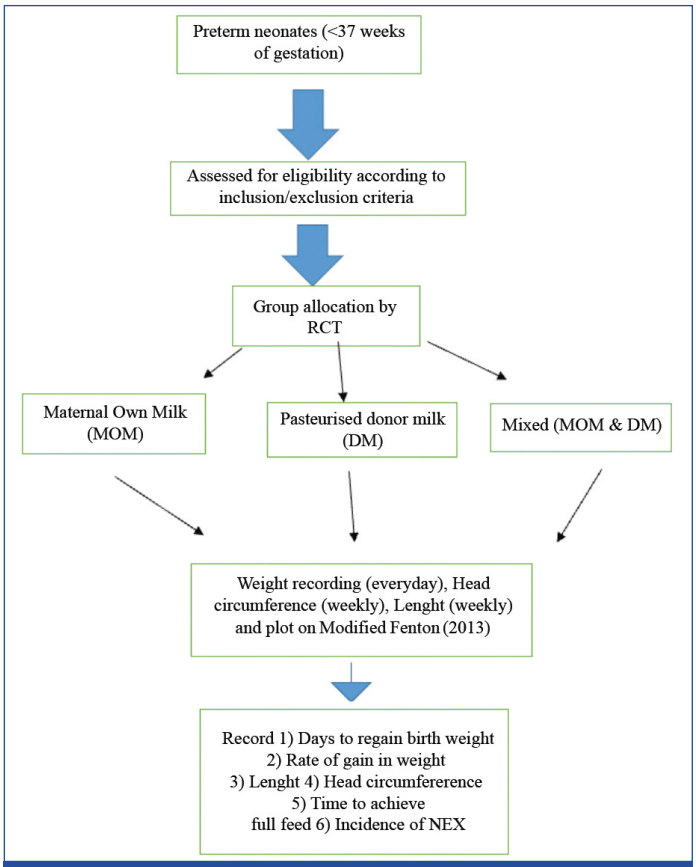
Estimated required sample sizes:

n1=25

n2=25

n3=25

The methodology used in the study in a concise manner is summarised in [Table/Fig-5].



[Table/Fig-5]: Flowchart showing study methodology.

Primary Outcomes:

- Days to Regain Birth Weight
- Rate of weight gain (average daily/weekly weight gain)
- Length (measured using an infantometer)
- Head Circumference {Occipitofrontal Circumference (OFC)}

Time to achieve full feed: The objective is to achieve full enteral feeding, targeting 150-180 mL/kg/day, within two weeks for infants born weighing less than 1000 g and within one week for those born weighing 1000-1500 g. This goal will be accomplished through the implementation of evidence-based feeding protocols. Achieving full enteral feeding promptly has been shown to lead to earlier removal of vascular catheters, a reduced incidence of sepsis and fewer catheter-related complications [29].

Secondary outcomes: Incidence of Necrotising Enterocolitis (NEC): For a definitive diagnosis of NEC, a key imaging test is an abdominal plain film series, consisting of anterior-posterior and left lateral decubitus views. This radiographic evaluation typically reveals distinctive signs of NEC, such as bowel dilation, pneumatosis intestinalis and portal venous air [30].

Morbidity rates: The incidence of complications such as vomiting, abdominal distension greater than 2 cm from baseline and reflux will be recorded for morbidity.

- Human Milk Fortifier (HMF)
- Feed intolerance episodes
- Daily skin-to-skin contact hours

Hospital stay outcomes: This includes discharge weight, length and head circumference.

Weight Growth Velocity (WGV): Weight Growth Velocity (WGV) is an appropriate index to use when assessing postnatal weight gain. The velocity standards for weight are presented as 1-month increments from birth to 12 months and as 2- to 6-month increments from birth to 24 months. Weight increments by birth-weight category, which are particularly useful for lactation management purposes, are presented in 1-week and 2-week intervals from birth to 60 days [31]. To calculate the neonate's WGV, the weight on the 10th day of the study will be divided by the weight on the 1st day of the study and this result will be divided by 10. The resulting number will then be multiplied by 1,000. The unit of the resulting number will be g/kg/day. Logistic regression will be used to compare the incidence of FI.

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) version 21.0 software will be used for data analysis. The normality of the data distribution will be investigated using the student's t-test. Analysis of Variance (ANOVA) will be used to compare anthropometric indices. A p-value of less than 0.05 will be considered significant.

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- For any images presented appropriate consent has been obtained from the subjects. NA

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