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The OPTI-GROWTH Study: Evaluating the Efficacy and Safety of Optilait Infant Formula in NICU Neonates

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Abstract

Background: This study evaluates the nutritional efficacy of Optilait, an infant formula designed for neonates, those admitted in Neonatal Intensive Care Units (NICUs) in Luanda, Angola. Recognizing that breast milk is the gold standard for infant nutrition, this research explores Optilait as a vital alternative when breastfeeding is insufficient or contraindicated. **Methodology:** A total of 29 infants, aged between birth and six months, were enrolled in a non-interventional, single-centre, prospective study over 28 days. The primary parameters measured were included gain in weight, height, and head circumference, recorded on a daily basis. **Results:** The study demonstrated statistically significant improvements in weight, with an overall gain of 39.06% from Day 1 to Day 28 ($p < 0.001$), alongside notable increases in head circumference (16.64%) and height (14.17%). Compliance with Optilait consumption was excellent, with all infants adhering to the prescribed intake. Six infants reported adverse events that were not directly associated with the formula. **Conclusion:** The findings suggest that Optilait provides a nutritionally effective alternative for infants requiring formula supplementation, addressing growth needs in a clinically vulnerable population.

Keywords

Infant Formula, Anthropometry, Neonatal Growth, Weight Gain, Head Circumference

1. Introduction

Breast milk is universally recognized as the optimal source of nutrition for infants, providing a perfect balance of nutrients and bioactive components essential for

growth, development, and immune support. It contains antibodies, enzymes, and hormones that help protect against infections and chronic diseases [1]. Exclusive breastfeeding (EBF) for the first six months of life is associated with reduced risk of gastrointestinal and respiratory infections, enhanced cognitive development, and long-term health benefits, including lower rates of obesity and type 2 diabetes [2]. The World Health Organization (WHO) and the American Academy of Paediatrics (AAP) advocate for EBF for the first six months, followed by continued breastfeeding alongside complementary foods for up to two years or beyond [3]. Breastfeeding also fosters a unique bond between the mother and infant, promoting psychological well-being and development [4].

Though breastfeeding is ideal, there are circumstances where breast feeding may not be possible or insufficient, necessitating safe and effective alternatives. According to the Indian Academy of Pediatrics (IAP) guidelines, these guidelines emphasize the importance of breastfeeding, recommending exclusive breastfeeding for the first six months, as per the World Health Organization. Continued breastfeeding with complementary foods is advised for at least 12 months by the American Academy of Paediatrics and the Academy of Nutrition and Dietetics. When breastfeeding is not feasible, infant formula serves as a substitute, designed to mimic breast milk's nutritional composition. While prioritizing breastfeeding, these guidelines recognize the necessity of alternatives in certain situations. Infant formulas are recommended when breastfeeding is contraindicated, insufficient, or not feasible [5]. These formulas are designed to mimic the nutritional composition of breast milk, providing essential macronutrients, vitamins, and minerals to support healthy growth and development of the infant [6]. The IAP and WHO recommend using formulas under medical guidance, particularly in vulnerable infants, such as preterm or low-birth-weight infants. Infant formula feed can be used as a sole nutrition source during the first six months and as a supplement alongside complementary feeding up to 12 months of age [7].

There are many formula feeds which are available in the market today and OPTILAIT, a brand of Shalina Healthcare, is one of the formula feeds which is designed to provide a balanced nutritional profile that supports the growth and development of infants from birth till 6 months of age, particularly those in neonatal intensive care units (NICUs). In addition, it is given to the infants in whom breastfeeding is contraindicated & who are unable to receive sufficient feed. OPTILAIT incorporates essential nutrients, including proteins, fats, vitamins, and minerals, tailored to meet the needs of infants who cannot be breastfed. The formula contains whole milk powder, oleic sunflower oil powder, hydrolysed whey protein, casein, skimmed milk powder, maltodextrin, mineral mix, vitamin mix, taurine, nucleotides L-Carnitine, Fructooligosaccharides (FOS), Galactooligosaccharides (GOS) and contains no added Sugar [8]. Aiming to ensure that OPTILAIT (Feed formula) meets the highest standard of nutrition and safety, a research study was designed to assess the improvement in weight gain, head circumference, height & safety of OPTILAIT in infants admitted to the NICU in Luanda, Angola.

2. Methodology

This study was a non-interventional, single-center, observational, prospective study conducted in accordance with routine clinical practice at the Neonatology department in Kapalanga Hospital in Luanda, Angola. The study involved 29 infants admitted to the Neonatal Intensive Care Unit (NICU) in Luanda, with data collection spanning over four weeks (28 days) from the time of admission.

After an appropriate consent infants who were born at term, singleton births, with a birth weight of ≥2500 grams, aged between birth and six months, and either not being breastfed or whose mothers had independently chosen exclusive formula feeding were enrolled. Exclusion criteria were congenital illnesses affecting growth, chronic malabsorption, significant prenatal or serious postnatal disease, minor parent(s), inability of caregivers to comply with study procedures, and no prior participation in any other clinical studies.

The primary endpoint for the study was growth expressed as weight gain in grams per day (Time frame 28 days). The secondary endpoints were growth in terms of body length body length (in centimetres), growth in terms of head circumference (in centimeters), compliance to study formula intake recording daily quantity consumed (in milliliters) in the feeding diary, and assessment of the occurrence of adverse events. All these parameters were measured from enrollment until infants are 28 days. Study nurse assisted to record all the relevant data as per the protocol requirements.

At the start of the study, baseline demographic details, including age, gender, pulse rate, respiratory rate, and method of delivery. Additionally, the weight, height & head circumference of each infant were recorded daily for the entire period of 28 days. The quantity of OPTILAIT consumed daily for the period of 28 days since the day of enrollment, and the daily dosage was adequately documented by the study nurse to ensure 100% compliance as per study protocol requirements. The use of Optilait was not part of the routine care before the patients were included in the study. Out of 29 participants enrolled in the study, 12 used the formula exclusively and 17 used the formula as a supplement. The mean dose of Optilait given to babies was 45.42 mL with a standard deviation of 18.92 mL per feed, per day. Adverse reactions to Optilait were documented separately. Microsoft Excel was used for data analysis, and basic statistical tests were applied to all efficacy measures. The primary efficacy data were analyzed using a paired t-test within the treatment group, with results expressed as mean ± standard deviation. A p-value < 0.05 was considered statistically significant. All statistical analyses were conducted using SPSS version 20.0.

Ethical Considerations: Informed consent was obtained by the investigator from a legally acceptable representative (LAR) before study enrollment of infants.

3. Results

3.1. Demographic and Baseline Physiological Characteristics

A total of 29 infants were enrolled in the study, with a mean age of 3.52 ± 2.91

days. The majority of the infants were male (51.7%), while 48.3% were female. The mode of delivery was predominantly normal vaginal delivery (72.4%), while 27.6% were delivered via Caesarean section. The gestational age of the participants was approximately from ≥ 37 weeks (0 day) to ≤ 42 weeks (0 day). The mean pulse rate at baseline was 139.41 ± 12.41 beats per minute (BPM), and the mean respiratory rate was 45.55 ± 8.17 cycles per minute (CPM). These parameters remained within normal physiological limits throughout the study period.

As shown in Figure 1, the age distribution of infants enrolled in the study. The age varied from newly born child to 11 days old infant. The mean age of children was 3.52 days with SD of 2.91 days.

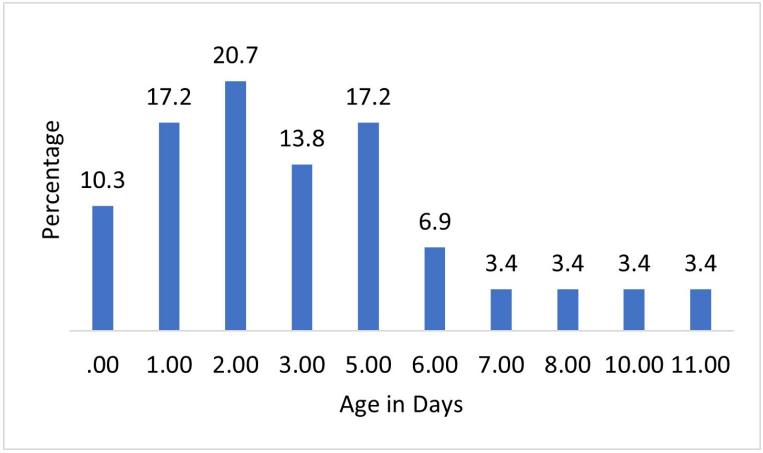

Figure 1. Age distribution of infants.

3.2. Growth Parameters

3.2.1. Weight Gain

The below Table 1 shows the mean weight and standard deviation of weight in infants on different days along with percentage improvement over a period of 28 Days. The table also shows the level of significance of differences in weight between

Table 1. Weight distribution of infants according to age.

Weight in Kg	Mean (Kg)	Std. Deviation (Kg)	Percentage Improvement	t test	P Value
Weight Day 1	2.56	0.79	8.20	8.805	<0.001
Weight Day 7	2.77	0.82			
Weight Day 7	2.77	0.82	10.11	10.42	<0.001
Weight Day 14	3.05	0.88			
Weight Day 14	3.05	0.88	7.54	7.741	<0.001
Weight Day 21	3.28	0.90			
Weight Day 21	3.28	0.90	8.54	6.55	<0.001
Weight Day 28	3.56	0.98			
Weight Day 1	2.56	0.79	39.06	15.535	<0.001
Weight Day 28	3.56	0.98			

infants during different days. As can be seen from the table, infants demonstrated a progressive and statistically significant increase in weight over the 28-day study. To summarize, there was an increase of weight by 8.20% between Day 1 and Day 7, 10.11% between Day 7 and Day 14, 7.54% between Day 14 and Day 21 and an increase of 8.54% between Day 21 and Day 28. The overall percentage increase in weight between Day 1 and Day 28 was 39.06%.

Table 2. Percentage improvement in weight from day 1.

Weight in Kg	Mean (Kg)	Std. Deviation (Kg)	Improvement from **Day 1**	Percentage Change from **Day 1**
Weight Day 1	2.56	0.79		
Weight Day 7	2.77	0.82	0.21	8.20
Weight Day 14	3.05	0.88	0.49	19.14
Weight Day 21	3.28	0.90	0.72	28.13
Weight Day 28	3.56	0.98	1.00	39.06

As shown in Table 2, quantitative data on the incremental weight gain of infants compared to their baseline weight (Day 1). The table includes:

- Absolute weight gain from Day 1 at each time point (e.g., infants gained an average of 0.21 kg by Day 7, 0.49 kg by Day 14, etc.).
- Percentage change in weight from Day 1, showing a gradual increase in weight with a total gain of 39.06% by Day 28.

This data, combined with the graphical representation, confirms the effectiveness of the formula in promoting significant weight gain, with all comparisons being statistically significant ($P < 0.001$).

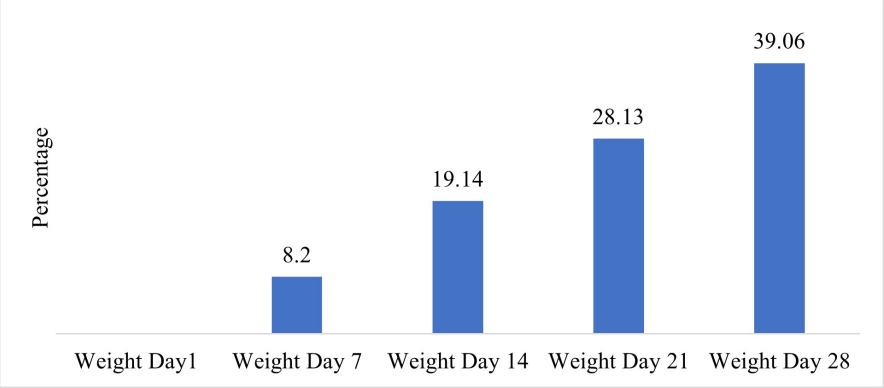

Figure 2. Percentage weight gain from day 1.

As shown in Figure 2, the weight gain in percentage from day 1 to day 28 of the study (after initiation of Optilait). It was seen that the mean or average increase in weight of the infant after 28 days of feeding with Optilait was 39.06%.

3.2.2. Head Circumference

As shown in Table 3, the mean Head Circumference (HC) and Standard deviation of HC of babies on different days along with the percentage improvement over a

period of 28 Days. Also, the table shows the levels of significance of differences in HC between different pair of days. As can be seen from Table 3, a consistent increase in HC was observed over time. There was an increase of 4.21% between Day 1 and Day 7, an increase of 4.97% between Day 7 and Day 14, an increase of 2.65% between Day 14 and Day 21 and an increase of 3.88% between Day 21 and Day 28. The overall percentage increase in HC between Day 1 and day 28 was 16.64%. All pairwise comparisons between mean of head circumferences of Day 1 and Day 7, Day 7 and Day 14, Day 14 and Day 21, Day 21 and Day 28, as well as the overall change of HC from Day 1 to Day 28, were statistically significant ($P < 0.001$).

Table 3. Head circumference according to days.

Head Circumference (HC) in cm	Mean (cm)	Std. Deviation (cm)	Percentage Improvement Within Pair	t test	P Value
HC-Day 1	33.77	3.95	4.21	8.273	<0.001
HC-Day 7	35.19	4.10			
HC-Day 7	35.19	4.10	4.97	9.985	<0.001
HC-Day 14	36.94	4.17			
HC-Day 14	36.94	4.17	2.65	4.007	<0.001
HC-Day 21	37.92	3.93			
HC-Day 21	37.92	3.93	3.88	6.752	<0.001
HC-Day 28	39.39	3.87			
HC Day 1	33.77	3.95	16.64	15.578	<0.001
HC-Day 28	39.39	3.87			

Table 4. Improvement from day 1 in head circumference.

Head Circumference (HC) in cm	Mean (cm)	Std. Deviation (cm)	Improvement from Day 1	Percentage Change from Day 1
HC-Day 1	33.77	3.95		
HC-Day 7	35.19	4.10	1.42	4.20
HC-Day 14	36.94	4.17	3.17	9.39
HC-Day 21	37.92	3.93	4.15	12.29
HC-Day 28	39.39	3.87	5.62	16.64

As shown in Table 4, detailed numerical data on the increase in head circumference from baseline (Day 1) to subsequent days. This data confirms a statistically significant increase in head circumference at every interval ($P < 0.001$), supporting the efficacy of Optilait in promoting head growth in infants over the study period.

Figure 3 illustrates the percentage increase in head circumference of infants at various time points over the 28-day study period. The graph visually represents the growth trend, showing a steady increase in head circumference from Day 1 to Day 28. The most significant growth increments appear between Day 7 and Day 14, after which the increase continues at a slightly steady rate and remains statistically significant ($P < 0.001$).

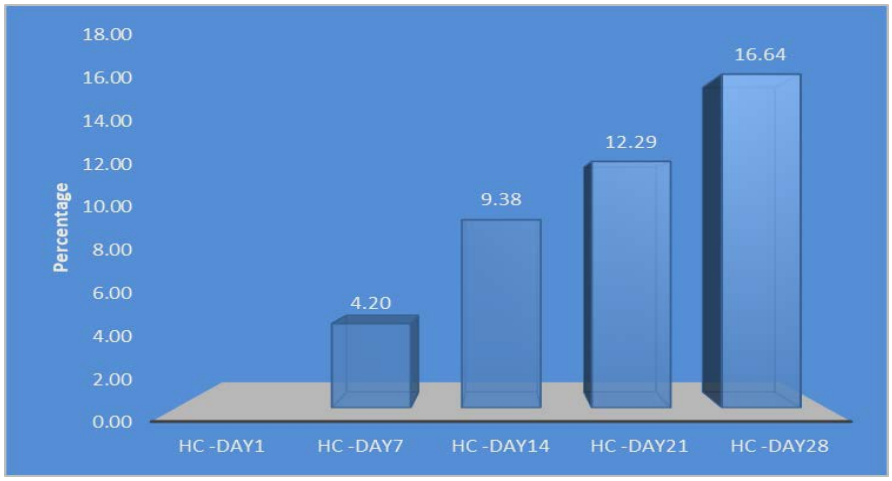

Figure 3. Percentage increase in Head Circumference on different days from baseline.

3.2.3. Length (Height) Growth

Table 5 presents data on the incremental increase in height (length) of infants over the 28-day study period.

Table 5. Height of infants during different days.

Height in cm	Mean (cm)	Std. Deviation (cm)	Percentage Improvement Within Pair	t test	P Value
Height-Day 1	40.59	5.00	3.32	8.588	<0.001
Height-Day 7	41.93	4.96			
Height-Day 7	41.93	4.96	4.21	7.029	<0.001
Height-Day 14	43.70	5.34			
Height-Day 14	43.70	5.34	2.66	6.086	<0.001
Height-Day 21	44.86	5.07			
Height-Day 21	44.86	5.07	3.31	5.588	<0.001
Height-Day 28	46.34	5.05			
Height-Day 1	40.59	5.00	14.17	15.115	<0.001
Height-Day 28	46.34	5.05			

3.3. Key Observations

- Infants showed a steady and significant increase in height over time.
- An increase in height of 3.32% was observed between Day 1 and Day 7.
- Similarly, an increase of 4.21% between Day 7 and Day 14, an increase of 2.66% between Day 14 and Day 21 and an increase of 3.31% between Day 21 and Day 28 was seen and documented.
- The overall percentage increase in Height between Day 1 and day 28 was 14.17%.
- Comparison of mean of heights between Day 1 to Day 7, Day 7 to Day 14, Day 14 to Day 21, Day 21 and Day 28, and between Day 1 to Day 28 are all statistically significant ($P < 0.001$).

This data highlights the nutritional adequacy of the formula in supporting proper growth and development in infants over the study period.

Table 6. Percentage improvement in height from day 1.

Height in cm	Mean (cm)	Std. Deviation (cm)	Improvement from **Day 1**	Percentage Change from **Day 1**
Height-Day 1	40.59	5.00		
Height-Day 7	41.93	4.96	1.34	3.31
Height-Day 14	43.70	5.34	3.11	7.66
Height-Day 21	44.86	5.07	4.27	10.52
Height-Day 28	46.34	5.05	5.75	14.17

As shown in Table 6, progressive increase in mean height over the 28-day study period in the Optilait study conducted in Angola. The mean height increased from 40.59 cm at Day 1 to 46.34 cm at Day 28, reflecting a total mean gain of 5.75 cm (14.17%). Incremental improvements were observed at each follow-up visit (Day 7, 14, and 21), indicating consistent growth throughout the study duration. The relatively stable standard deviation across time points suggests uniform growth trends among participants.

These growth patterns were compared with expected neonatal growth trajectories reported in the literature, where term neonates generally demonstrate weight gain of approximately 20 - 30 g/day, length gain of around 0.8 - 1.0 cm/week, and head circumference growth of approximately 0.5 - 0.8 cm/week during early infancy. The observed findings in the present study were therefore considered clinically meaningful in this nutritionally vulnerable NICU population.

3.4. Compliance with Optilait Formula Feeding

One of the primary objectives of this study was to evaluate compliance with the prescribed Optilait formula feeding regimen. All infants (100%) were adherent to the feeding protocol, consuming the formula as recommended. The mean daily intake of Optilait was 45.42 ± 18.92 mL, with a median intake of 38.10 mL. The distribution of formula intake varied widely, ranging from 18 mL to 96 mL per day.

3.5. Other Findings

3.5.1. Indications for Formula Feeding

The most common reasons for initiating formula feeding in this study were prematurity (20.69%), maternal employment (17.24%), and low breast milk production (10.34%). Other contributing factors included maternal infections such as HIV (6.90%) and Hepatitis B (3.45%), inadequate neonatal suction (3.45%), and recommendations from neonatologists for weight control (3.45%).

3.5.2. Adverse Events

A total of six infants (20.6%) experienced adverse events during the study. The

most frequently reported adverse effects included gastrointestinal reflux (16.66%), jaundice (16.66%), respiratory distress requiring orogastric tube feeding (16.66%), and abdominal cramps (16.66%). Other events included difficulties with swallowing due to prematurity (16.66%) and suspected hydrocephalus or spina bifida (16.66%). All adverse events reported were of mild severity and were managed as per regular routine clinical practice with no relapse. No serious adverse events were recorded, and all infants successfully completed the study.

4. Discussion

The OPTI-GROWTH study evaluated the efficacy and safety of the new infant formula (Optilait), in neonates admitted to the NICU in Luanda, Angola. The study demonstrated consistent improvements in key growth parameters, including weight, height, and head circumference, suggesting that Optilait effectively supports growth during infancy.

The findings indicate a steady increase in weight over the study period, with an overall weight gain of 39.06% from Day 1 to Day 28. Each interval showed statistically significant weight improvements ($P < 0.001$). Similarly, head circumference increased by 16.64%, and height increased by 14.17%, with progressive improvements observed throughout the study period. These findings suggest that Optilait may support growth and nutritional needs in neonates requiring formula supplementation, particularly in situations where adequate breastfeeding is not possible or sufficient.

The study also assessed the tolerability of Optilait, where it was found to be safe, along with being efficacious. Out of the 29 infants enrolled, 6 infants experienced adverse events, including reflux, jaundice, respiratory distress, difficulty swallowing due to prematurity, possible hydrocephalus, and abdominal cramps. While these cases were observed, it remains unclear if they were directly related to Optilait or underlying neonatal conditions. In spite of these adverse events, all 29 infants adhered to the prescribed intake, confirming good compliance.

Approximately 55.2% of infants required medications during the study period, primarily due to neonatal sepsis, neonatal hypoxia, prematurity, or protocol-based treatments. Despite these pre-existing or concurrent conditions, Optilait displayed significant improvement across all growth parameters.

The most common reasons for using infant formula were prematurity (20.69%), maternal factors such as working mothers (17.24%), and low breast milk production (10.34%). Other cases included maternal infections (HIV, Hepatitis B) and neonatal feeding difficulties. These findings highlight the importance of having a reliable infant formula for neonates who cannot exclusively breastfeed.

The growth outcomes observed in this study align with findings from previous research on infant feeding methods. Studies have shown that breastfed infants typically gain weight more slowly than formula-fed infants in the first year of life, with differences in weight patterns continuing even after introducing complementary foods. This is consistent with our observations, where formula-fed in-

fants demonstrated significant increases in weight, head circumference, and height over the 28-day study period [9] [10]. Moreover, research comparing growth patterns among infants fed different types of protein hydrolysate formulas indicates that the degree of protein hydrolysis can impact growth outcomes. A study observed that infants fed extensively hydrolysed protein formulas exhibited growth patterns similar to those of breastfed infants, whereas those fed intact cow's milk protein formulas had higher weight-for-length z-scores. This suggests that the protein composition and processing of infant formulas can influence growth trajectories, aligning with our findings that the specific formulation of Optilait supports healthy growth [11].

The study provides evidence that Optilait is a beneficial alternative to breast milk for neonates requiring supplementation. The study focused on a clinically vulnerable population (NICU-Based Cohort), providing valuable insights into the role of this formula feed in infants with growth concerns. Also, it assessed multiple growth parameters (weight, head circumference, and height) to ensure a holistic evaluation of infant growth. Additionally, a 100% compliance rate indicates excellent tolerability of the formula, reinforcing its practical applicability in clinical settings.

However, the study's limitations include its small sample size (n = 29) and its single-centric design. Even though this may limit generalizability, it ensures consistency, reducing potential confounders that might arise in multicenter studies with varying protocols.

5. Conclusion

Optilait was associated with improvements in weight gain, head circumference, and height among neonates requiring formula supplementation, along with a high level of compliance throughout the study period. The observed growth changes were statistically significant and suggest that Optilait may provide nutritional support for infant growth and development in situations where supplementation is required. While mild adverse events were reported, they were manageable and did not appear to affect overall tolerability. Overall, these findings suggest that Optilait may be a well-tolerated formula option for infants who require nutritional supplementation.

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Conflicts of Interest

Author confirms that the study was conducted in accordance with applicable ethical standards, and that the interpretation of data and final manuscript content were carried out with scientific integrity and without undue influence.

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