

NUTRICIA
FortiniTM

Evidence Booklet

FOR US HEALTHCARE PROFESSIONALS

Research Summary of Fortini™



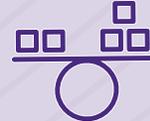
30 calories/fl oz energy- & nutrient-dense term infant formula
specifically calibrated for term infants with or at risk of **failure to thrive**



Clinically shown to promote catch-up growth in disease- and non-disease-related growth failure^{1,2}



Equivalent tolerability to 20 kcal/fl oz standard infant formula^{3,4}



Nutritionally complete with the right balance of fluid, protein, and energy



Powered by protein: 2.6 g of protein per 100 kcal; meets WHO/FAO/UNU guideline for 10.3% of energy from protein to support lean tissue gain for catch-up growth⁵



Made in Europe, supported by 7 clinical studies, and trusted for over 20 years[†]

ABBREVIATIONS

cEB:cumulative energy balance	PICU:.....pediatric intensive care unit
cNB:cumulative nitrogen balance	RCT.....randomized, controlled trial
CHD.....congenital heart disease	RTF:.....ready to feed
DRI:.....dietary reference intake	SEM:.....standard error of the mean
ESF:energy-supplemented formula	SIF:.....standard infant formula
ENDF:.....energy- and nutrient-dense formula	SPE(Phe):.....splanchnic phenylalanine extraction
FTT:.....failure to thrive	WFA:.....weight-for-age
NO:.....nitric oxide	*stands for:.....statistically significant p values

Fortini is for the dietary management of term infants and young children from 0 to 18 months of age or up to 19.8 lbs (9 kg) with or at risk of growth failure, increased energy requirements, and/or fluid restrictions due to conditions such as:

- Congenital heart disease
- Chronic lung disease
- Respiratory syncytial virus
- Neurological syndrome or neuro-disabilities
- Cystic fibrosis
- Non-organic failure to thrive

† In other countries, Fortini is known as Infatrini.

1. Clarke, et al. J Hum Nutr Diet. 2007;20:329-39. 2. Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10. 3. Cui, et al. JPEN J Parenter Enteral Nutr. 2018;42:196-204. 4. van Waardenburg, et al. Clin Nutr. 2009;28:249-55. 5. World Health Organization; Food and Agriculture Organization of the United Nations; United Nations University. Protein and amino acid requirements in human nutrition: report of a joint FAO/WHO/UNU expert consultation. 2007.



Publication & Study Purpose		Population, Design & Length of Intervention	Takeaways	Page
Tolerance				
2006 Evans S, <i>et al.</i> J Hum Nutr Diet. 19:191-7.	Evaluate tolerance to feeding Fortini to infants with failure to thrive (FTT) when given from day 1 compared to gradual introduction.	<ul style="list-style-type: none"> • 30 infants (2-43 weeks) with FTT • Double blind RCT • 2 weeks 	 <ul style="list-style-type: none"> • Well tolerated in infants with FTT when given from day 1 • A gradual introduction may benefit infants <12 weeks 	4
Tolerance and growth				
2007 Clarke SE, <i>et al.</i> J Hum Nutr Diet. 20:329-39.	Compare effects of Fortini vs. an energy-supplemented formula (ESF) in infants with FTT. Measures included nutritional and biochemical response, anthropometry, intake and tolerance.	<ul style="list-style-type: none"> • 49 infants with FTT • Open-label RCT • 6 weeks 	 <ul style="list-style-type: none"> • As well tolerated as ESF • Supported nutrient intake and catch-up growth of infants with FTT 	5
Tolerance, energy intake & protein status				
2009 van Wardenburg DA, <i>et al.</i> Clin Nutr. 28:249-55.	Compare effects of Fortini with standard infant formula (SIF) on: <ul style="list-style-type: none"> • nutrient intake • cumulative energy and nitrogen balances • plasma essential amino acid profile • whole body protein balance, • metabolism of arginine, needed for nitric oxide synthesis • tolerance and safety, as secondary outcomes 	<ul style="list-style-type: none"> • 18 PICU infants with respiratory failure due to viral bronchiolitis • Double blind RCT • 5 days 	 <ul style="list-style-type: none"> • Safe and as well tolerated as SIF in the PICU • Improved energy and nutrient intake vs. a SIF 	6
2011 de Betue CT, <i>et al.</i> Arch Dis Child. 96:817-22.			 <ul style="list-style-type: none"> • Promoted anabolic state earlier in critically ill infants receiving exclusively Fortini vs. exclusively SIF 	7
2013 de Betue CT, <i>et al.</i> Am J Clin Nutr. 98(4):907-16.				8
3 unique publications from 1 clinical trial				
Tolerance, nutrient intake & nitrogen balance				
2018 Cui Y, <i>et al.</i> JPEN J Parenter Enteral Nutr. 42:196-204.	Evaluate tolerance and nutrition impacts of Fortini vs. SIF in infants for 5 days following surgery for congenital heart disease (CHD).	<ul style="list-style-type: none"> • 50 infants with CHD • Double blind RCT • 5 days 	 <ul style="list-style-type: none"> • Well tolerated • Faster realization of nutritional goals • Achieved positive nitrogen balance sooner (d2 vs. d5) after CHD surgery 	9
Tolerance and growth				
2019 Eveleens RD, <i>et al.</i> J Hum Nutr Diet. 32:3-10.	Describe the use of Fortini in infants with prolonged PICU admissions by assessing weight outcomes and digestive tolerance.	<ul style="list-style-type: none"> • 70 infants • Retrospective chart review • Minimum 2 weeks Fortini use 	 <ul style="list-style-type: none"> • Well tolerated • Supported weight improvement in majority of infants with prolonged PICU stays 	10
Tolerance and weight gain				
2020 Scheeffe V, <i>et al.</i> JPEN J Parenter Enteral Nutr. 44(2):348-54.	Evaluate effect of Fortini vs. normocaloric SIFs on mean daily weight gain and digestive tolerance in infants following CHD surgery.	<ul style="list-style-type: none"> • 59 infants • Open-label RCT • 30 days 	 <ul style="list-style-type: none"> • Well tolerated • Supported weight gain following CHD surgery. • Findings included higher weight gain variation rate, less frequent use of antibiotics, and trend toward shorter hospital length of stay vs. SIF group 	11

THERAPEUTIC AREA



Failure to Thrive



Congenital Heart Disease



Critical Illness

SHOULD HIGH ENERGY INFANT FORMULA BE GIVEN AT FULL STRENGTH FROM ITS FIRST DAY OF USAGE?



bit.ly/FORTINI1

Evans S, Twaissi H, Daly A, Davies P, MacDonald A. 2006

PURPOSE

To assess whether an energy- and nutrient-dense (1 kcal/mL) infant formula (ENDF), intended for the nutritional management of infants with failure to thrive (FTT) can be well tolerated at full strength from day 1 versus a gradual introduction.

DESIGN

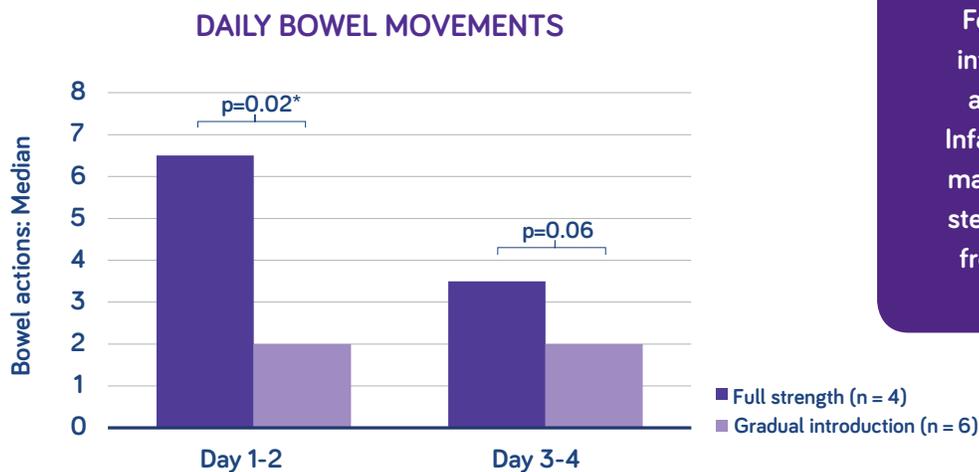
Thirty infants with a median age of 14.5 weeks were recruited in the study. Inclusion criteria were age (0-12 months) and a diagnosis of FTT in order for them to be eligible for receiving an ENDF (Fortini). The infants were assigned at random to either full-strength ENDF from day 1 (n=18) or diluted ENDF which gradually increased to reach full strength by day 3 (n=12). Daily records of volume of feed consumed as well as bowel movements and vomiting episodes were kept for 14 days. Anthropometric measurements (including weight, length, head circumference and mid-upper arm circumference) were taken at baseline and after 14 days.

OUTCOMES

Higher numbers of bowel movements were observed on days 1 and 2 for the group who received the ENDF at full strength versus the gradual introduction group (p=0.02). In particular, subjects younger than 12 weeks experienced more bowel movements on days 1 & 2 with ENDF at full strength (p=0.04). Finally, there was a correlation between higher total energy intake (kcal/kg) and more frequent bowel movements for days 1-4 (p=0.01). No statistically significant differences between the two groups were seen for growth or vomiting.

CONCLUSIONS

Administering ENDF at full strength from day 1 to infants with FTT was found to be generally well tolerated. Infants younger than 12 weeks of age could potentially benefit from a gradual introduction of ENDF to avoid more frequent bowel movements.



Fortini was well tolerated in infants with FTT when given at full strength from day 1. Infants younger than 12 weeks may benefit from a gradual or stepwise introduction to avoid frequent bowel movements.

RANDOMIZED COMPARISON OF A NUTRIENT-DENSE FORMULA WITH AN ENERGY-SUPPLEMENTED FORMULA FOR INFANTS WITH FALTERING GROWTH



bit.ly/FORTINI2

Clarke SE, Evans S, MacDonald A, Davies P, Booth IW. 2007

PURPOSE

It has been common practice to nourish infants with failure to thrive (FTT) by supplementing routine infant formula with added energy. This approach increases energy density but negatively impacts the protein-to-energy ratio. It further introduces the risks of mixing errors in preparing the feeding and of microbial contamination. This trial aimed to evaluate the effectiveness of an energy- and nutrient-dense formula (ENDF) compared to a standard formula supplemented with energy (ESF) in infants with failure to thrive (FTT).

DESIGN

Forty-nine infants with FTT were randomized in this open, parallel study that lasted 6 weeks. The test group received ENDF (Fortini, 1 kcal/mL) and the control group received ESF (1 kcal/mL). Measures collected included anthropometrics, laboratory values, formula intake, and stool and emesis frequencies.

OUTCOMES

There was a significant increase in median weight-for-age (WFA) z-score for the ENDF group (+0.29 z-score, $p < 0.007$). Compared to the ESF group, protein intake for the ENDF group was 42% higher, and vitamin and mineral intakes were 15-40% higher. This was in spite of no significant differences in feeding volumes or energy intake, and there were no differences in tolerance. Blood urea levels in the ESF group dropped by 50% during the trial, indicative of better protein-to-energy ratio in ENDF vs. ESF feeding. The ENDF group maintained mean serum urea within normal limits, and had no significant decrease in z-score for length vs. ESF group.

CONCLUSIONS

An infant formula enriched in protein and energy that provides appropriate levels of micronutrients should be favored for infants with FTT over the practice of adding energy to standard infant formula.

MEDIAN ANTHROPOMETRIC CHANGES WITH SIGNIFICANT DIFFERENCES WITHIN AND/OR BETWEEN GROUPS

	Within ENDF group (n=26) (n=14 male) (n=12 female)*	Within ESF group (n=23) (n=12 male) (n=11 female)*	Between groups†
WFA z-scores			
	0.29 P = 0.007	0.49 P = 0.006	P = 0.26
MALES	0.21 P = 0.02	0.40 P = 0.24	P = 0.98
FEMALES	0.32 P = 0.16	0.86 P = 0.01	P = 0.12
Length-for-age z-scores			
	-0.18 P = 0.24	-0.28 P = 0.01	P = 0.30
MALES	-0.16 P = 0.42	-0.80 P = 0.002	P = 0.02

*Within-group differences: Wilcoxon signed rank test

†Between-group differences: Mann-Whitney test

Female length-for-age z-scores not significantly different, not shown.

Fortini is as well-tolerated as ESF and supports improvement in WFA z-score of infants with FTT. Fortini was “safe and well tolerated, provided improved nutrient intakes, enhanced blood urea levels, and a trend toward better growth (notably for boys) when compared with the ESF.”

CRITICALLY ILL INFANTS BENEFIT FROM EARLY ADMINISTRATION OF PROTEIN AND ENERGY-ENRICHED FORMULA: A RANDOMIZED CONTROLLED TRIAL



bit.ly/FORTINI3

van Waardenburg DA, de Betue CT, van Goudoever JB, Zimmermann LJ, Joosten KF. 2009

PURPOSE

Nutritional support improves outcome in critically ill infants but is impeded by fluid restriction, gastric intolerance and feeding interruptions. Protein- and energy-enriched infant formulas may help to achieve nutritional targets earlier during admission and promote anabolism.

DESIGN

Randomized controlled design. Infants with respiratory failure due to RSV-bronchiolitis received a protein- and energy-enriched formula (ENDF, Fortini, n=8) or a standard infant formula (SIF, n=10) for 5 days after admission. Primary outcome: nutrient delivery, energy and nitrogen balance and plasma amino acid concentrations. Secondary outcome: tolerance and safety.

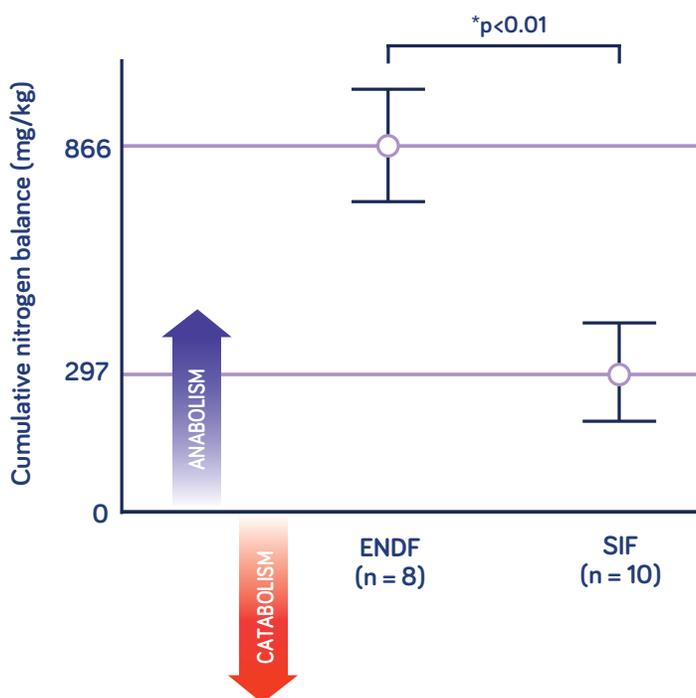
OUTCOMES

Nutrient intakes were higher in ENDF infants and met dietary reference intakes (DRI) on day 3-5. In SIF infants DRI was met on day 5 only. Cumulative nitrogen balance (cNB) and energy balance (cEB) were higher in ENDF infants compared to SIF infants (cNB: 866 ± 113 vs. 296 ± 71 mg/kg; cEB: 151 ± 31 and 26 ± 17 kcal/kg, both $p < 0.01$). Essential amino acid levels were higher in ENDF infants but within reference limits whereas below these limits in SIF infants. Both formulas were well tolerated.

CONCLUSIONS

Early administration of a protein and energy-enriched formula in critically ill infants is well tolerated, promotes a more adequate nutrient intake and improves energy and nitrogen balance without adverse effects.

CUMULATIVE NITROGEN BALANCE, DAYS 2-5



Fortini is safe and as well tolerated as SIF in the PICU. Intakes of nutrients were higher in Fortini infants, meeting dietary reference intake levels on days 3-5, which were only met by SIF infants on day 5.

INCREASED PROTEIN-ENERGY INTAKE PROMOTES ANABOLISM IN CRITICALLY ILL INFANTS WITH VIRAL BRONCHIOLITIS: A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL



bit.ly/FORTINI4

de Betue CT, van Waardenburg DA, Deutz NE, van Eijk HM, van Goudoever JB, Luiking YC, Zimmermann LJ, Joosten KF. 2011

PURPOSE

The preservation of nutritional status and growth is an important aim in critically ill infants, but difficult to achieve due to the metabolic stress response and inadequate nutritional intake leading to negative protein balance. This study investigated whether increasing protein and energy intakes can promote anabolism. The primary outcome was whole body protein balance, and the secondary outcome was first pass splanchnic phenylalanine extraction (SPE(Phe)), a measure of diet-derived amino acids.

DESIGN

A double-blind randomized controlled trial. Infants (n=18) admitted to the pediatric intensive care unit (PICU) with respiratory failure due to viral bronchiolitis were randomized to continuous enteral feeding with a protein- and energy-enriched formula (ENDF, Fortini) (n=8; 3.1 ± 0.3 g protein/kg/24 h, 119 ± 25 kcal/kg/24 h) or a standard infant formula (SIF) (n=10; 1.7 ± 0.2 g protein/kg/24 h, 84 ± 15 kcal/kg/24 h; equivalent to recommended intakes for healthy infants <6 months). A combined intravenous-enteral phenylalanine stable isotope protocol was used on day 5 after admission to determine whole body protein metabolism and SPE(Phe).

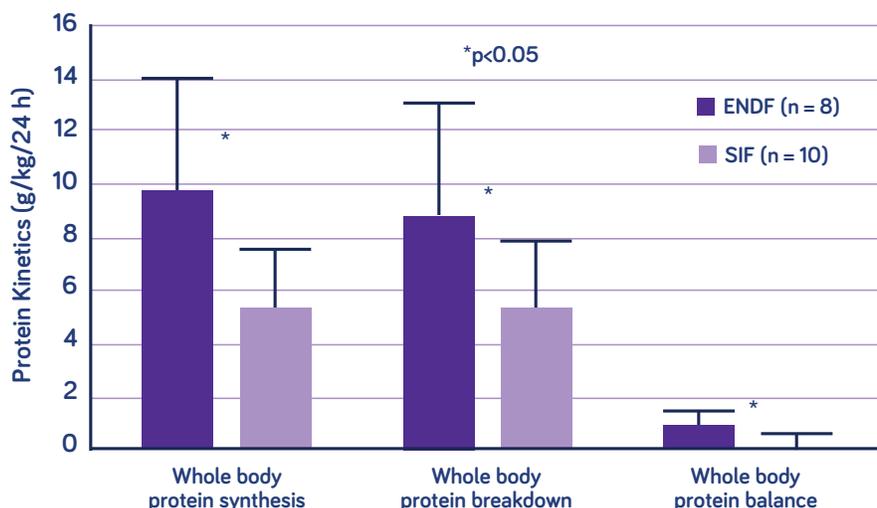
OUTCOMES

Protein balance was significantly higher with ENDF than with SIF (ENDF: 0.73 ± 0.5 vs. SIF: 0.02 ± 0.6 g/kg/24 h) resulting from significantly increased protein synthesis (ENDF: 9.6 ± 4.4 , SIF: 5.2 ± 2.3 g/kg/24 h), despite significantly increased protein breakdown (ENDF: 8.9 ± 4.3 , SIF: 5.2 ± 2.6 g/kg/24 h). SPE(Phe) was not statistically different between the two groups (ENDF: $39.8 \pm 18.3\%$, SIF: $52.4 \pm 13.6\%$).

CONCLUSIONS

Increasing protein and energy intakes promotes protein anabolism in critically ill infants in the first days after admission. Since this is an important target of nutritional support, increased protein and energy intakes should be preferred above standard intakes in these infants.

RATES OF PROTEIN KINETICS IN BOTH STUDY GROUPS ON DAY 5



“The present study is the first to show that protein anabolism, an important target of nutritional support in critically ill infants, can be achieved within the first days after admission to the PICU by increasing enteral protein and energy intakes above dietary reference levels using [Fortini].”

ARGININE APPEARANCE AND NITRIC OXIDE SYNTHESIS IN CRITICALLY ILL INFANTS CAN BE INCREASED WITH A PROTEIN-ENERGY-ENRICHED ENTERAL FORMULA



bit.ly/FORTINI5

de Betue CT, Joosten KFM, Deutz NEP, Vreugdenhil ACE, van Waardenburg DA. 2013

PURPOSE

The amino acid arginine is required for protein synthesis and the production of nitric oxide (NO), an important signalling molecule. It is conditionally essential in critical illness, as arginine production does not meet requirements in states of increased metabolic requirements, e.g. severe inflammation. The present study explored if an energy- and nutrient-dense formula (ENDF), which contains more arginine than a standard infant formula (SIF) due to the increased protein content, can increase arginine appearance and NO synthesis.

DESIGN

Infants with respiratory failure due to viral bronchiolitis were randomly assigned to receive either an ENDF (Fortini) or SIF for 5 days. A 2 hour stable isotope protocol was used to measure arginine kinetics and metabolism. Phenylalanine and tyrosine tracers were used to assess whole body protein synthesis.

OUTCOMES

The stable isotope tracer protocol was conducted in 18 patients (n=8 ENDF, n=10 SIF). Both formulas were well tolerated. Energy, protein and arginine intakes were significantly higher in the ENDF group. Arginine appearance and NO synthesis was found to be significantly higher with the ENDF group compared to the SIF group (p=0.003). Whole body protein synthesis and net whole body protein synthesis (whole body protein synthesis – whole body protein breakdown) were also significantly higher in the ENDF group.

CONCLUSIONS

This study demonstrates that arginine availability can be increased in critically ill infants with the use of ENDF. In addition to increased arginine appearance and NO synthesis, the ENDF increased protein turnover, synthesis and breakdown, achieving an anabolic state in these infants despite severe acute illness.

MEAN (\pm SEM) WHOLE-BODY PROTEIN METABOLISM IN CRITICALLY ILL INFANTS RECEIVING ENDF (N = 8) OR SIF (N = 10).



Fortini resulted in increased arginine availability (p=0.012) and NO synthesis (p=0.003) vs. SIF. Plasma arginine levels were not significantly increased in the Fortini group vs. SIF group.

EFFECTS AND TOLERANCE OF PROTEIN AND ENERGY-ENRICHED FORMULA IN INFANTS FOLLOWING CONGENITAL HEART SURGERY: A RANDOMIZED CONTROLLED TRIAL



bit.ly/FORTINI6

Cui Y, Li L, Hu C, Shi H, Li J, Gupta RK, Liang H, Chen X, Gong S. 2018

PURPOSE

For infants undergoing surgery for congenital heart defects (CHD), nutrition support is a critical component for positive outcomes. Energy- and nutrient-dense formula (ENDF) may help meet nutrient recommendations and support healing from surgery. However, tolerance and impacts of increased energy and protein delivery for this population has not been well researched. This trial aimed to study the tolerance and nutritional response to ENDF compared to a standard infant formula (SIF) in infants for 5 days following surgery for CHD.

DESIGN

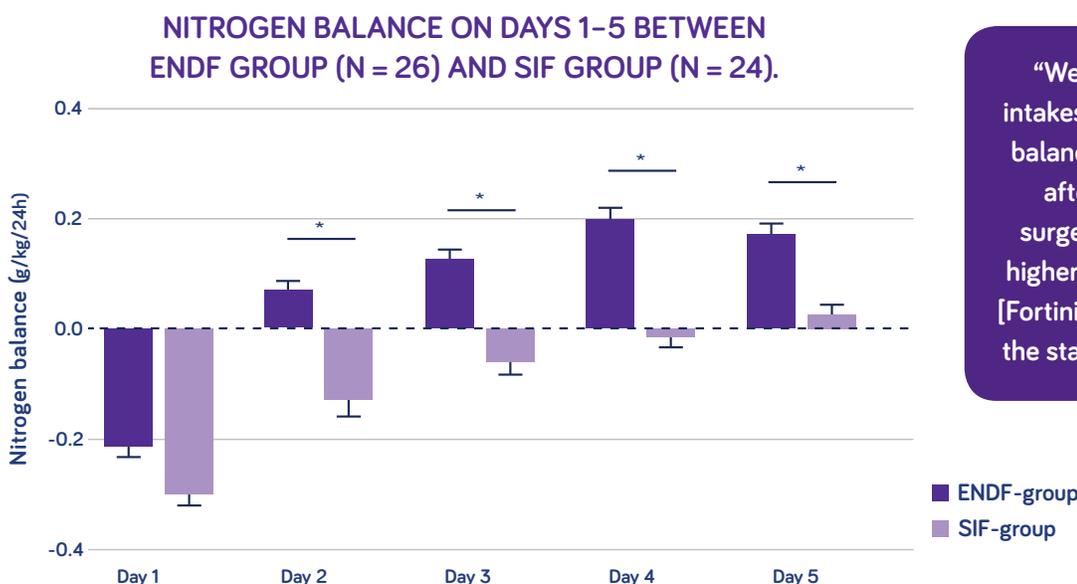
Infants (n=50) were randomized to receive either a test formula (ENDF, Fortini, n=26) or control formula (SIF, n=24). Tolerance and daily volume intakes were recorded. Plasma levels of amino acids were measured, and cumulative nitrogen balance (cNB) and cumulative energy balance (cEB) were calculated.

OUTCOMES

ENDF group had significantly higher intake of nutrients after day 1, with all subjects in this group meeting adequate nutrient intakes by day 2. Positive cNB was met in the ENDF group from day 2: the SIF group did not achieve this until day 5. Many essential amino acid concentrations increased significantly more in ENDF group. ENDF group did not experience significantly higher incidences of adverse events, with one exception for tolerable diarrhea (hazard ratio with multivariate adjustment, 3.16; 95% confidence interval, 1.24-8.01).

CONCLUSIONS

In the immediate days following surgery for CHD in infants, administering ENDF early was tolerated equally as well as SIF. Feeding an ENDF was also effective in meeting adequate nutrient intakes sooner, providing higher intake of nutrients, and achieving positive nitrogen balance sooner.



“We found that nutrient intakes and positive nitrogen balance... in the early stage after congenital heart surgery, were significantly higher and met earlier in the [Fortini] group compared with the standard formula group.”

WEIGHT IMPROVEMENT WITH THE USE OF PROTEIN AND ENERGY ENRICHED NUTRITIONAL FORMULA IN INFANTS WITH A PROLONGED PICU STAY



bit.ly/FORTINI7

Eveleens RD, Dungen DK, Verbruggen SCAT, Hulst JM, Joosten KFM. 2019

PURPOSE

To achieve nutritional intake goals in critically ill infants is difficult. The use of an energy- and nutrient-dense formula (ENDF) is one way to help minimize risk of inadequate nutrient intake, since the use of standard infant formula for this patient group provides inadequate nutrient levels. The present study aimed to assess weight gain and gastrointestinal events in infants with an extended pediatric intensive care unit (PICU) stay while they were receiving ENDF (Fortini) for an extended period.

DESIGN

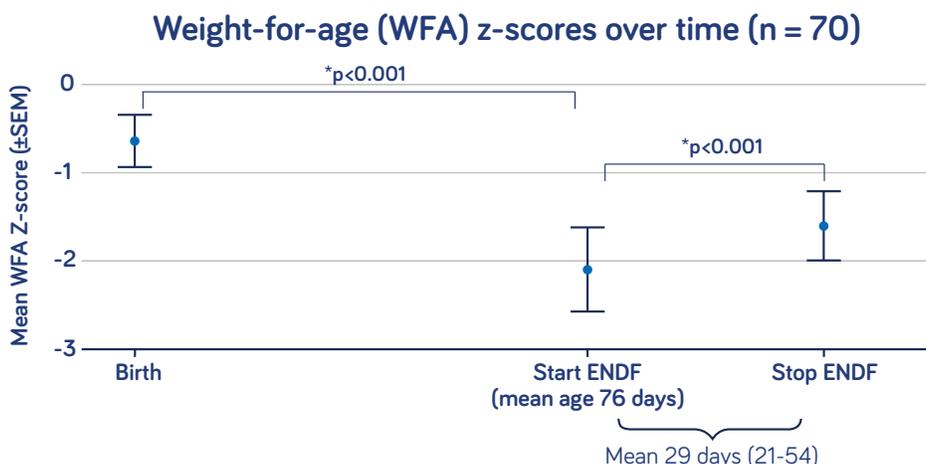
Retrospective data from infants who were admitted to PICU between 2007-2017 (Erasmus Medical Center, Rotterdam, The Netherlands) were analyzed. Data reviewed included demographics, nutritional intakes and the duration of ENDF use. Part of the inclusion criteria were the specific age of the infants (not younger than 37 post-menstrual weeks and not older than 12 months), an extended PICU stay (≥ 14 days) as well as a minimum of 14 days feeding with ENDF. Human milk was the preferred feeding choice, but when human milk was not available, ENDF was started at the discretion of the clinician. Weight-for-age (WFA) z-scores were calculated at the start and at the end of ENDF use and compared to birth WFA z-scores. Feeding tolerance of ENDF was assessed using markers including gastric residual volume and symptoms such as vomiting, constipation and diarrhea.

OUTCOMES

Seventy infants met the inclusion criteria of the study. Overall, the median use of ENDF was 30 days (interquartile range [IQR]: 21–54) and median PICU duration was 50 (IQR: 35–83) days. Post-cardiac surgery, respiratory, cardiac and neurological conditions were the main reasons for admission. Mean WFA z-score significantly increased during ENDF use (0.48, SD 1.10, $p < 0.001$). Further analysis revealed that lower WFA z-scores when starting ENDF were associated with greater increases in WFA z-score following ENDF use. The number of infants with a WFA z-score < -2 had decreased from 33 (47%) to 23 (33%) after the use of ENDF. Overall, 93% of infants gained weight and 71% of infants showed an increased WFA z-score. Only 5 infants had constipation and 3 infants were treated for vomiting.

CONCLUSIONS

The use of ENDF was overall well tolerated and significantly supported growth markers (weight gain & WFA z-scores) of a vulnerable patient group of critically-ill infants, for an extended PICU stay.



Fortini is well tolerated and supports weight improvement in the majority of infants with prolonged PICU stays.

TOLERABILITY AND EFFECTS OF THE USE OF ENERGY-ENRICHED INFANT FORMULA AFTER CONGENITAL HEART SURGERY: A RANDOMIZED CONTROLLED TRIAL



bit.ly/FORTINIB

Scheeffe VA, Pires Ricachinevsky C, Tha'is Freitas A, Salamon F, Nunes Rodrigues FF, Goldani Brondani T, Tomasi Sutil A, Ferreira CHT, da Silveira Matte U, Reverbel da Silveira T. 2020

PURPOSE

Children with congenital heart disease (CHD) frequently experience undernutrition, which can negatively impact outcomes after surgery. Increased energy intake following CHD surgery has been linked with improved outcomes. This trial evaluated the impacts of using an energy- and nutrient-dense formula (ENDF) compared to standard infant formulas (SIFs) during the 30 days following surgery for CHD.

DESIGN

Children undergoing surgery for CHD in a tertiary care hospital in southern Brazil between March 2017 and December 2017 were eligible for this randomized controlled trial. Subjects in the test group were fed with ENDF (Fortini, 1 kcal/mL), and those in the control group were fed with an SIF at the standard energy density (0.67 kcal/mL). The individual responsible for anthropometric measurements was blind to each subject's random group assignment.

OUTCOMES

Fifty-nine patients were randomized: 29 to the test group (ENDF) and 30 to control (SIF). No statistically significant differences were seen between groups following randomization regarding gender, age, anthropometry or surgical risk classification. After intervention, the ENDF group demonstrated significantly higher weight-for-age z-score and weight gain variation rate compared to the SIF group. Similar frequency of general GI side effects was seen between groups, although diarrhea was more frequent in the ENDF group. Findings for the ENDF group included less frequent use of antibiotics ($p=0.047$) and a trend toward shorter hospital length of stay vs. the SIF group.

CONCLUSIONS

This trial found that use of ENDF is well tolerated by children following surgery for CHD while also supporting weight gain. Potential impacts seen on reducing length of hospital stay and use of antibiotics in this trial could be confirmed in future trials with larger sample sizes.

OUTCOMES AND FINDINGS BY GROUP AFTER COMPLETION

	ENDF	SIF	p Value
WFA z-score	-1.57 ± 0.2	-2.69 ± 0.2	0.042 [†]
Length of stay, days	14.4 ± 1.84	20.19 ± 2.56	0.057 [†]
Mechanical ventilation duration	90.3 ± 23.5	108.4 ± 26.3	0.65 [†]
Oxygen at day 30, n (%)	0	5 (31.2)	0.01 [†]
Diuretics at day 30, n (%)	11 (55)	16 (100)	<0.01 [†]
Antibiotic use among intent-to-treat, n (%)	16/29 (55.2)	24/39 (80)	0.047 [†]
% kcal formula at day 30	92.27 ± 2.5	73.25 ± 3.4	0.14 [‡]

*Mean ± SEM; Student t-test

[†]Fisher's exact test

[‡]Wald's χ^2

Fortini is well tolerated and supports positive weight gain in patients for 30 days after CHD surgery.

Other findings from this trial - less frequent use of antibiotics and a trend toward shorter hospital length of stay for the Fortini group - suggest further potential benefits.

