

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



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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.”

Fortini is for the dietary management of term infants and young children from 0 to 18 months of age or up to 198 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. Fortini is known in other countries as Infatini. For US healthcare professionals

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