Effects of a nutrient dense infant formula on the growth and tolerance of infants compared to current practice in Spain.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29641

Source
NTR

Brief title
INGROTO

Health condition

(non-) organic growth failure

Sponsors and support

Primary sponsor: Numico Research B.V.
Source(s) of monetary or material Support: Numico Research B.V.

Intervention

Outcome measures

Primary outcome

Increase in Z-score for length at 6 weeks relative to baseline.

Secondary outcome

Anthropometrics, gastrointestinal tolerance, fecal microbiology and dietary intake.

Study description

Background summary

The aim of this study is to compare the effects, with regard to growth, of a nutrient dense infant formula to the effect of current practice in Spain in infants requiring a high-energy feed. Therefore, subjects will receive either a nutrient dense infant formula or current practice for a period of 6 weeks. An optional 6-week extension period is offered to all subjects completing the initial 6-week study period. Baseline anthropometrics measurements will be collected and repeated outcomes will be measured during hospital visits at week 3, 6, 9, and 12. Tolerance to the feed will be recorded weekly and a 3-day food diary will be completed to evaluate the intake of other foods/drinks. Subject's blood and stool samples will be collected at baseline, 6 weeks, and 12 weeks for the analysis of safety parameters and fecal microbiota respectively.

Study objective

A nutrient dense infant formula promotes growth more effectively than current practice.

Study design

Baseline, and follow up measurements at 3 weeks, 6 weeks (and 9 weeks and 12 weeks, in case of optional extension period) after baseline.

Intervention

Duration intervention: 6-12 weeks. Intervention group: a high energy, high protein and nutrient dense, nutritionally complete, ready-to-use feed for infants 0-12 months. Control group: constitutes all infant formulas used as part of "current practice" in Spain for infants with increased energy requirements and/or fluid restrictions.

Contacts

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Eligibility criteria

Inclusion criteria

1. Infants aged 0 to 9 months;

2. Infants with increased energy requirements and/or fluid restrictions and/or with indication for using high-energy feeds;

3. The infants must be new consumers of oral high-energy feeds;

4. Infants must have an expected requirement for the study product for at least 6 weeks, with an expected study product intake of, on average, at least 50% of their energy intake;

5. Written parental informed consent must be available.

Exclusion criteria

1. Infants with cow's milk intolerance, major gastrointestinal hepatic or renal dysfunction, or inherited metabolic disorders including galactosaemia are excluded for this study;

2. Investigator's uncertainty about the willingness or ability of the caretaker to comply with the protocol requirements;

3. Participation in any other studies with investigational or marketed products concomitantly or within two weeks prior to entry into this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2008
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	30-01-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1156
NTR-old	NTR1199
Other	Numico Research B.V. : 100.153
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A