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

Gepubliceerd: 30-01-2008 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29641

Bron
NTR

Verkorte titel
INGROTO

Aandoening

(non-) organic growth failure

Ondersteuning

Primaire sponsor: Numico Research B.V.
Overige ondersteuning: Numico Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2008
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-01-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A