Single arm, open label, multi-centre intervention trial to evaluate the tolerance and acceptability of a high energy, nutrient enriched infant formula.

Gepubliceerd: 16-11-2012 Laatst bijgewerkt: 18-08-2022

There will be no issues with regards to tolerance in relation to the switch from the current to the new high energy, nutrient enriched infant formula.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27027

Bron
Nationaal Trial Register

Verkorte titel
SATIN study

Aandoening

malnutrition, failure to thrive

Ondersteuning

Primaire sponsor: Danone Research – Centre for Specialised Nutrition
Overige ondersteuning: Danone Research – Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerance and acceptability.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial the tolerance and acceptability of a new high energy, nutrient enriched infant formula will be evaluated in children receiving the current high energy, nutrient enriched infant formula.

Doel van het onderzoek

There will be no issues with regards to tolerance in relation to the switch from the current to the new high energy, nutrient enriched infant formula.

Onderzoeksopzet

V1 (Day -2) and V2 (Day 8).

Onderzoeksproduct en/of interventie

During a 3-days baseline period subjects will receive the current high energy, nutrient enriched infant formula. GI symptoms, stool frequency, stool consistency and the amount of current formula consumed will be recorded on a daily basis in a diary. During the following 7-day intervention period subjects will consume the study formula (new high energy, nutrient enriched infant formula). GI symptoms, stool frequency, stool consistency and the amount of study formula consumed will be recorded on a daily basis in a diary.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 0 to 18 months (including 0 and 18 months);

2. 37 to 42 weeks gestation at birth;

3. Currently receiving a high energy, nutrient enriched infant formula (current Infatrini) for at least 7 days prior to the baseline visit (day -2);

4. Expected to require a high energy infant formula for at least 10 days after baseline visit;

5. Consuming, on average, at least 50% of their energy intake from the study feed;

6. Either enterally fed (naso-enteric tube, gastrostomy, jejunostomy) or orally fed (bottle fed);

7. Written informed consent from parents/ guardians that have legal custody of the child;

8. Parents/ guardians should have good knowledge of Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Body weight > 9kg;

2. Proven cow‟s milk allergy;

3. Lactose intolerance;

4. Galactosaemia;

5. Other medical or dietary contraindication to a polymeric, high energy, nutrient enriched infant formula (eg major hepatic or renal dysfunction);

6. BMR vaccination performed within 14 days prior to baseline visit, any other vaccination performed within 48 hours prior to baseline visit or any vaccination planned within 10 days after baseline visit;

7. Any surgery planned within 10 days after baseline visit;

8. Investigator's uncertainty about the willingness or ability of the parent/caregiver to comply with the protocol requirements;

9. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2012
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-11-2012
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	NL3524
NTR-old	NTR3708
Ander register	Danone Research – Centre for Specialised Nutrition : ITI.9.C/B/0
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A