Study on the effects of an infant formula on stool in healthy infants

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The study products will result in different stool consistency compared to reference product

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

Samenvatting

ID

NL-OMON19941

Bron
NTR

Verkorte titel
CONDOR

Aandoening

Stool consistency
Gastrointestinal (dis)comfort

Ondersteuning

Primaire sponsor: FrieslandCampina
Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Stool consistency
- Protein and fat digestion

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Around 55% of infants <6 months of age suffer from gastrointestinal problems. Especially, passing of hard stools, which can lead to constipation, cramps and crying, is a concern. As digestive discomfort is associated with problems in digestion of proteins and lipids, the quality of the diet is an important factor.

Objective:

To improve fat and protein absorption and prevent digestive problems in infants this study aims to assess effects of processing of infant formula and milk fat on stool consistency and digestion related outcomes.

Study Design:

Randomized double blind reference control parallel study with three arms: 1) alternative processing, 2) alternative processing + milk fat, 3) reference formula

Doel van het onderzoek

The study products will result in different stool consistency compared to reference product

Onderzoeksopzet

Baseline visit, week 4, 8, 12, and 16 (endline): anthropometry, diaries, questionnaires, stool samples

Onderzoeksproduct en/of interventie

Commercial available infant formula as a reference

Adapted infant formula I different processing

Adapted infant formula II different processing and different fat blend

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Healthy and term infants (gestational age >= 37 and <= 42 weeks)

- Infants who are partially formula fed (> 500 mL formula/day) or exclusively formula fed

- At least 30 infants per arm (n=90 in total) are exclusively formula fed (mothers who have chosen not to breastfeed or mothers who ceased breastfeeding for at least 1 week before inclusion)

- Birth weight between 2.5 and 4.5 kg

- Age < 40 days

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Congenital condition and/or previous or current illness that could interfere with study

- Known or increased risk of cow's milk allergy and/ or lactose intolerance (i.e. one of the biological parents and or siblings diagnosed with cow's milk allergy, asthma, hay fever, etc.)

- Having a mother suffering from diabetes during pregnancy

- Participation in another clinical trial

- Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements (including to fill in the diaries and to wait with introducing weaning foods until 4 months of age)

- Use of antibiotics at the time of screening, or during the past two weeks

- Being one of multiple birth (i.e. twins, triplets)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2017
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-03-2017
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	NL5867
NTR-old	NTR6291
Ander register	FrieslandCampina : CETD00

Resultaten