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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19941

Source
NTR

Brief title
CONDOR

Health condition

Stool consistency
Gastrointestinal (dis)comfort

Sponsors and support

Primary sponsor: FrieslandCampina
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

- Stool consistency

- Protein and fat digestion

Secondary outcome

- Stool frequency

- Stool amount

- Stool color

- Gastrointestinal symptoms

- Crying time

- Fecal parameters

Study description

Background summary

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

Study objective

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

Study design

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

samples

Intervention

Commercial available infant formula as a reference

Adapted infant formula I different processing

Adapted infant formula II different processing and different fat blend

Contacts

Public
61 Quality Rd
I.M.S. Tan-Khouw
[default] 618818
Singapore
+65 6419 8474
Scientific
61 Quality Rd
I.M.S. Tan-Khouw
[default] 618818
Singapore
+65 6419 8474

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-03-2017
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	NL5867
NTR-old	NTR6291
Other	FrieslandCampina : CETD00

Study results