Microbiota composition in healthy termed infants consuming infant formulae with different fat blends.

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Infant formulae with higher levels of milk fat result in improved microbiota composition as compared to standard formula.

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

Samenvatting

ID

NL-OMON27114

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Microbiota modulation, absorption of fat and calcium, gut comfort, stool consistency

Ondersteuning

Primaire sponsor: FrieslandCampina N.V.
Overige ondersteuning: FrieslandCampina N.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Microbiota composition

Toelichting onderzoek

Achtergrond van het onderzoek

Breast milk represents optimum nutrition for full-term babies throughout infancy. An important component of breast milk is fat which covers approximately 50% of its caloric content. Almost 98% of fat in breast milk is in the form of triacylglycerols (TAGs). Palmitic acid (C16:0) is the major saturated fatty acid in the TAGs of breast milk, corresponding to 20-25% of its total fatty acid content. More than 60% of palmitic acid in breast milk is esterified to the second carbon (sn-2 or beta-position) of glycerol in the TAGs and as such it is called beta-palmitate. Is has been proved by various clinical trials that this specific structure of human breast milk's fat content can contribute in the overall gut comfort. In addition, it is known that beta-palmitate can increase the Lactobacillus and bifidobacteria counts in infant feces.

When breast-feeding is not adequate, feasible or desirable, infant formulae are an alternative. Vegetable oils, that are traditionally used as matrices for the preparation of infant formulae, have a lower content of beta-palmitate (i.e. 5-20% of their total palmitic acid content) compared to breast milk. On the other hand, cow's milk content of beta-palmitate, although lower than that of breast milk, is approximately 40%. Recent studies have shown that increasing the content of beta palmitate in infant formula can improve the absorption of several nutrients, such as fat and calcium, as well as alter the microbial composition increasing the number of beneficial bacteria and their corresponding metabolites.

For these reasons, increasing the sn-2 palmitic acid content in milk formulae, by using cow's milk fat, could potentially lead to a higher absorption of palmitic acid, total fatty acids and calcium, as well as to beneficial effects in the microbial composition of infants' feces in comparison to milk formulae containing TAGs derived mainly from vegetable oils which have a high concentration of sn-1 and sn-3 palmitic acid.

Doel van het onderzoek

Infant formulae with higher levels of milk fat result in improved microbiota composition as compared to standard formula.

Onderzoeksopzet

Microbiota composition: stool sample analysis
time point: every two weeks; at the end of wash-out period, Period I and Period II.
Fatty acids absorption: stool sample analysis and food intake diary
time point: every two weeks; at the end of wash-out period, Period I and Period II.
Calcium absorption: stool sample analysis and food intake diary
time point: every two weeks; at the end of wash-out period, Period I and Period II.
Gut comfort: ROME III questionnaire and Amsterdam Infant Stool Scale
time point: baseline and every two weeks; at the end of wash-out period, Period I and Period

II.
Body weight & recumbent length
time point: baseline and every two weeks; at the end of wash-out period, Period I and Period II.

Onderzoeksproduct en/of interventie

Following recruitment and before treatment allocation, all infants will be fed with a standard formula for two weeks and this will be considered as a wash-out period. After the washout period, half of the infants will be randomly allocated to receive for two weeks (Period I) the standard formula, while the other half of the infants will be randomly allocated to receive a milk fat formula. After two weeks, the two groups will be crossed-over to receive the other formulae for the subsequent two weeks (Period II).

Contactpersonen

Publiek

FrieslandCampina Nederland B.V.
Prescilla Jeurink

+31615122071

Wetenschappelijk

FrieslandCampina Nederland B.V.
Prescilla Jeurink

+31615122071

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Full-term, healthy infants (born at gestational age ≥37 weeks).
- "Appropriate for gestational age" birthweight (i.e. 10th centile ≤ Birth weight ≤ 90th centile).
- Age at enrolment: between 9th-14th 16th week
- Exclusively formula fed infants at least two weeks before recruitment and during the entire

intervention period.
- Parents willing and agreeing to initiate complementary feeding after the end of endpoint measurements, i.e. after the completion of the 5.5th month of age
- Parents willing to collect stools and fill in all study questionnaires and diaries during the entire intervention period
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Severe acquired or congenital diseases, mental or physical disorders, any symptoms of allergy (including cow¡¯s milk allergy).
- No parents or siblings with documented CMA allergy, diagnosed by a doctor.
- Use of probiotics, antibiotics or other medication that treats or causes GI symptoms and/or affect appetite at the time of screening or at any time throughout the study period (these infants will be considered as drop-outs).
- Use of medication(s) known or suspected to affect fat digestion, absorption and/or metabolism; nutritional supplements; suppositories; medication that may suppress or neutralize gastric acid secretion and gut mobility at the time of screening or at any time throughout the study period (these infants will be considered as drop-outs).
- Participation in another clinical trial.
- Any type of mixed feeding (i.e. combination of formula with breastfeeding in any proportion) and/or complementary feeding during the intervention.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2019

Aantal proefpersonen:	14
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-06-2019
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	NL7815
Ander register	FrieslandCampina Innovation : CCFAT00

Resultaten