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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27114

**Source**
NTR

**Brief title**
N/A

**Health condition**

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

### Sponsors and support

**Primary sponsor:** FrieslandCampina N.V.
**Source(s) of monetary or material Support:** FrieslandCampina N.V.

### Intervention

### Outcome measures

**Primary outcome**

Microbiota composition

**Secondary outcome**

Fatty acids absorption, Calcium absorption and gut comfort

# Study description

### Background summary

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.

### Study objective

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

### Study design

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.

**Intervention**

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).

# Contacts

**Public**
FrieslandCampina Nederland B.V.
Prescilla Jeurink

+31615122071
**Scientific**
FrieslandCampina Nederland B.V.
Prescilla Jeurink

+31615122071

# Eligibility criteria

## Inclusion criteria

- 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

### Exclusion criteria

- 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.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-04-2019 |
| Enrollment: | 14 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 19-06-2019 |
| 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 | NL7815 |
| Other | FrieslandCampina Innovation : CCFAT00 |

## Study results