Comparative fat absorption in healthy termed infants consuming infant formulae with different fat blends.

No registrations found.

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

Summary

ID

NL-OMON23088

Source
NTR

Health condition

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

Fatty acids absorption

Secondary outcome

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 (or â-position) of glycerol (sn-2) in the TAGs and as such it is called â-palmitate. Is has been proved by various clinical trials that this specific structure of human breast milk's fat content can contribute in the absorption of fat and minerals, as well as overall gut comfort.

When breast-feeding is not adequate, feasible or desirable, infant formulae are the next alternative. Vegetable oils, that are traditionally used as matrices for the preparation of infant formulae, have a lower content of â-palmitate (i.e. 5-20% of their total palmitic acid content) compared to breast milk. On the other hand, cow's milk content of â-palmitate, although lower than that of breast milk, is approximately 40%.

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, 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 fatty acids absorption as compared to standard formula.

Study design

Fatty acids absorption:

stool sample analysis and food intake diary

timepoint: 2 and 4 weeks

Calcium absorption:

stool sample analysis and food intake diary

timepoint: 2 and 4 weeks

Gut comfort:

ROME III questionnaire and Amsterdam Infant Stool Scale

timepoint: 0, 2 and 4 weeks

Body weight & recumbent length

timepoint: 0, 2 and 4 weeks.

Intervention

Following recruitment and before treatment allocation all infants will be fed with a standard formula and this will be considered as a wash-out period. After the washout period, at week 0, half of the infants will be randomly allocated to receive for 2 weeks (Period I) the standard formula, while the other half of the infants will be randomly allocated to receive a milk fat formula. After 2 weeks, the two groups will be crossed-over to receive the other formulae for the subsequent 2 weeks (Period II).

Contacts

Public
FrieslandCampina Innovation Centre
Bronland 20

Wageningen 6708 WH
The Netherlands
0031 6 13248135
Scientific
FrieslandCampina Innovation Centre
Bronland 20

Wageningen 6708 WH
The Netherlands
0031 6 13248135

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 week

- Exclusively formula fed infants before 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 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:	Pending
Start date (anticipated):	05-12-2017
Enrollment:	44
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-12-2017
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	NL6702
NTR-old	NTR6872
Other	FrieslandCampina Innovation : LLLP00

Study results