An exploratory study to measure the postprandial plasma triglyceride levels in breastfed or formula fed healthy infants.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24649

Source
Nationaal Trial Register

Brief title
EAGLE 1

Health condition

Healthy term infants

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition / UMC Groningen
Source(s) of monetary or material Support: Danone Research / Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Postprandial total plasma triglyceride levels at baseline and 30, 60, 90, 120, 180 or 240 minutes after baseline.

Secondary outcome

Differences in total plasma triglyceride levels between 2 feeding regimen (formula feeding vs. breastfeeding), measured at baseline and 30, 60, 90, 120, 180 and 240 minutes after baseline.

Study description

Background summary

Childhood overweight and obesity are increasing rapidly in the world's population with long-term health risks including adult obesity, diabetes type 2 and cardiovascular related diseases. Therefore, preventing childhood overweight and obesity serves reducing health-risks in later life. However, little is known about the factors encouraging early weight gain but it is being established that breast milk has a small but significant protective effect in regards to long-term weight gain over formula milk. Currently, no knowledge is available about the digestion and absorption of nutritional lipids in healthy term infants. Therefore, determining in this study postprandial plasma triglyceride levels in breastfed or formula fed healthy infants will help establish readout parameters and most conclusive time points that will be useful for future trials aiming at improving existing infant milk formula with the long-term aim to prevent childhood obesity.

Study objective

The postprandial plasma triglyceride levels will be different in breastfed compared to formula fed infants.

Study design

1 Examination day (of in total 1).

Intervention

Infants that are on full formula feeding will join the formula fed group, fully breastfed infants will join the breastfeeding reference group.

On the examination day 2 blood samples will be withdrawn via heel prick from each infant. Examination starts with withdrawal of the first blood sample in all infants (= baseline), followed by a feeding. For the second blood sample, infants are randomly grouped into subsamples of 5 infants per feeding regimen to have blood withdrawn either at 30, 60, 90, 120, 180 or 240 minutes after baseline.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy and full-term infants (gestational age > 37 and < 42 weeks);

2. Birth weight within the normal range for sex and gestational age (10th to 90th percentiles according to locally applicable growth charts);

3. 60 days of age or older;

4. Body weight appropriate for the age of 8 weeks and sex (10th to 90th percentiles according to locally applicable growth charts);

5. Written informed consent of both parent(s)/legal guardian(s).

Exclusion criteria

1. Infants with known congenital diseases or malfunctions e.g. gastrointestinal malformations, haemophilia;

2. Infants having received medical treatment with antibiotics and/or pain medication like paracetamol which may be included in cough syrup or other mixtures) within 4 days before examination;

3. Infants with abnormal growth (too slow or too fast weight gain) within the 10th to 90th percentiles of locally applicable weight-for-age charts for either boys or girls;

4. Infants needing a special diet other than standard cow's milk-based infant milk formula;

5. Infants having a mother suffering from known hepatitis B, HIV, high blood-pressure, hyperlipidaemia or diabetes;

6. Infants having an overweight (BMI > 27) mother prior to her first pregnancy;

7. Infants with any historical participation in any other study involving investigational or marketed products;

8. Investigator's uncertainty about the willingness or ability of the parent(s)/legal guardian(s) to comply with the protocol requirements and instructions.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	11-05-2010

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	NL2199
NTR-old	NTR2323
Other	Danone Research : Met.2.C/D/6
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N.A