An exploratory study to evaluate the effect of a new study product on early programming in healthy infants.

No registrations found.

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

Summary

ID

NL-OMON21169

Source
NTR

Brief title
EAGLE 2

Health condition

Healthy term infants

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Digestion and absorption, measured as blood lipid parameters.

Secondary outcome

N/A

Study description

Background summary

This study aims to investigate the impact of the new infant formula compared to a standard infant formula primarily on blood lipid parameters, and in addition on safety and tolerance. The study is designed with a run-in of 1-7 weeks and wash out period of 5 days on a currently marketed standard formula. On 2 examination days 2 blood samples will be withdrawn via heel prick from each infant, one day
after run-in period (Visit 2) one day after wash-out period (Visit 5).

Brief summary of results:
This study was prematurely terminated.The sample size was insufficient to perform a statistical comparison. All infants included so far completed the study and no safety issues were reported.

Study objective

The investigational formula will be equivalent to the control formula with regard to the postprandial blood lipid parameters.

Study design

1. Visit 1/Screening (age < 7 weeks);

2. Visit 2 (age 8 weeks) phone call (age 9 weeks);

3. Visit 3 (age 15 weeks);

4. Visit 4 (age 15 weeks);

5. Visit 5 (age -15 weeks+ 5 days), phone call (age 16 weeks).

Intervention

7 weeks randomised on either investigational or control product. The investigational product is a new formula containing CLM. The control product is a standard formula.

The investigational product is a new formula containing a “Complex Lipid Matrix, (CLM). The control product is a standard infant formula. The 7 weeks intervention starts at the age of 8 weeks and ends at the age of 15 weeks. Subjects are randomised on either investigational or control product. Until the age of 8 weeks, infants consume a run-in product, a currently market standard infant formula. After the age of 15 weeks, they get a wash-out product for 5 days, which is the same as run-in.

CLM, in short: "Complex Lipid Matrix" (CLM), are large fat droplets stabilized by added phospholipids.

In total, the nutrient content of the new formula is (except for the content of phospholipids) the same as the nutrient content of the control formula, only the fat droplets are bigger (closer to droplets in breast milk).

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Eligibility criteria

Inclusion criteria

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

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

3. Age 7 weeks at screening;

4. Body weight appropriate for the individual age and sex at screening (10th to 90 percentiles according to applicable growth charts);

5. Infants who are fully formula fed or have started the transition from breast to formula-feeding (indicated by the feeding of at least one bottle of infant formula in the past) and are planning to stop breastfeeding voluntarily by
infant's age of 7 weeks;

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

Exclusion criteria

1. Infants not on full formula feeding at the age of 7 weeks (to be answered latest at the age of 8 weeks (visit 2));

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

3. Current or previous illnesses which could interfere with the study (e.g. prolonged severe diarrhoea, regurgitation);

4. Infants with abnormal growth (too slow (<_-1SD) or too fast (> +1SD) weight gain) within the 10th to 90th percentiles of applicable weight-for-age charts for either boys or girls;

5. Infants at high risk to develop an atopic disease (at least one parent or sibling with manifest atopic symptoms of hay fever, asthma or atopic dermatitis);

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	08-02-2011
Enrollment:	28
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-01-2011
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	NL2593
NTR-old	NTR2721
Other	Danone Research : MET.3.C/D
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A