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

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

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

Samenvatting

ID

NL-OMON21169

Bron
NTR

Verkorte titel
EAGLE 2

Aandoening

Healthy term infants

Ondersteuning

Primaire sponsor: Danone Research - Centre for Specialised Nutrition
Overige ondersteuning: Danone Research - Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Digestion and absorption, measured as blood lipid parameters.

Toelichting onderzoek

Achtergrond van het onderzoek

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 On 2 examination days 2 blood samples will be withdrawn via heel prick from each infant, one day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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	08-02-2011
Aantal proefpersonen:	28
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:	27-01-2011
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	NL2593
NTR-old	NTR2721
Ander register	Danone Research : MET.3.C/D
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A