A safety and growth study with a new fat blend.

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Based on the human milk composition, Nutricia Research has developed a new infant formula with a new fat blend, more similar to that of human milk. This new formula is currently being studied for safety and its effects on growth. The comparator…

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

Samenvatting

ID

NL-OMON21391

Bron
NTR

Verkorte titel
Mercurius

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

To investigate equivalence of weight gain from randomisation until the age of 17 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study infant formula containing a new fat blend is compared with the same infant formula containing the standard fat blend.

The main parameter being studied is growth. Furthermore, gastrointestinal tolerance and safety are studied. The results are also compared to a breastfeeding reference group.

The infants will be included in the study until they are 35 days of age, study product intake will be until they are 4 months of age. There will be a follow-up period of two weeks after last product intake. Subsequently, subjects will be asked if they are willing to participate in an optional extension visit at 12 months of age.

During the intervention period, parents will be asked to fill in a diary with information on some of the parameters, and a questionnaire. Furthermore, they will be asked to collect a stool sample 2 to 3 times during the study. Voluntary blood draw can be taken at 3 and 12 months of age.

Doel van het onderzoek

Based on the human milk composition, Nutricia Research has developed a new infant formula with a new fat blend, more similar to that of human milk. This new formula is currently being studied for safety and its effects on growth.

The comparator used in the study is a standard infant formula containing the standard fat blend.

Onderzoeksopzet

1. V2 (Week 4);

2. V3 (Week 8);

3. V4 (week 13);

4. V5 (Week 17);

5. V6 (12 months).

Onderzoeksproduct en/of interventie

Duration of intervention: 13-17 weeks.

Intervention group: Standard infant formula containing the new fat blend.

Control group: Standard infant formula containing the standard fat blend.

Reference group (no intervention): Human milk.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy term (gestational age >= 37 1/7 and <= 42 6/7 weeks);

2. Age <= 35 days (preferably as soon as possible after birth);

3. Birth weight within normal range (10th to 90th percentile);

4. Exclusively formula fed (mothers who have chosen not to breastfeed or mothers who ended breastfeeding by time of inclusion);

OR

Exclusively breastfed (mothers willing to exclusively breastfeed at least till 13 weeks of age

(and preferably till 17 weeks of age);

5. Written informed consent from parent(s) and/or legal guardian, aged ≥ 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known current or previous illnesses/conditions or intervention which could interfere with the study or its outcome parameters;

2. Mother known to suffer from hepatitis B or human immunodeficiency virus (HIV) with a minimum number of formula fed infants ≤ 14 days

3. Need to be fed with a special diet other than standard (non hydrolysed) cow¡®s milk-based infant formula;

4. Currently participating or have participated in any other study involving investigational or marketed products;

5. Incapability of the parent(s) to comply with study protocol or investigator's uncertainty about the willingness or ability of the parent(s) to comply with the protocol requirements.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-09-2012
Aantal proefpersonen:	313
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	02-11-2012
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	NL3521
NTR-old	NTR3683
Ander register	Danone Research : EPI.1.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

1. Heijning, B.v.d., et al., 51st ESPGHAN Annual Meeting. Journal of Pediatric Gastroenterology and Nutrition, 2018. 66: p. 1110-1111.
2. Breij, L.M., et al., ESPGHAN 49th ANNUAL MEETING of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition. Journal of Pediatric Gastroenterology and Nutrition, 2016. 62: p. 867-868.

3. Breij, L.M., et al., An infant formula with large, milk phospholipid-coated lipid droplets containing a mixture of dairy and vegetable lipids supports adequate growth and is well tolerated in healthy, term infants. Am J Clin Nutr, 2019. 109(3): p. 586-596.