Fermented infant formula with prebiotics study.

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The mean weight gain of healthy infants receiving the study formula(s) during the first months of life is equivalent to the mean weight gain of healthy infants receiving the control formula(s).

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

Samenvatting

ID

NL-OMON25687

Bron
Nationaal Trial Register

Verkorte titel
FIPS

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

Weight gain in grams per day from study entry until 17 weeks of age.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study, new infant formulae combining the above ingredients will be tested with respect to growth and tolerance in healthy term infants. For the participants the study will last 15-19 weeks, including 5 hospital visits and 1 phone call.

At this first visit, baseline data are collected. Further study visits are conducted at 4, 8, 13, and 17 weeks of age. At each visit, data on growth are collected. Parents will be asked to record data on tolerance in the 7-day period prior to the study visits. Moreover, stool samples are collected either during or directly after the first visit, and just before the final visit. Two weeks after the final visit, a follow-up phone call takes place.

Doel van het onderzoek

The mean weight gain of healthy infants receiving the study formula(s) during the first months of life is equivalent to the mean weight gain of healthy infants receiving the control formula(s).

Onderzoeksopzet

The study will take 5 hospital visits and 1 phone call.

Onderzoeksproduct en/of interventie

Duration of intervention: 15-19 weeks;

1. Intervention groups: Cow's milk-based fermented infant formulae with prebiotics (combination of two pre-existing products which stimulate digestion);

2. Control groups: Cow's milk-based fermented/non-fermented infant formulae with/without prebiotics.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy, term (gestational age ¡Ý 37 and ¡Ü 42 weeks) infants;

2. Birth weight between 2,5-4,5 kg. These data is derived from WHO growth curves to look at group between 10th and 90th percentile;

3. Age ¡Ü 28 days;

4. Parents' or guardian's aged >18 years, written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Breastfeeding;

2. Congenital condition and/or previous or current illness that could interfere with study;

3. Known or increased risk of cow¡¯s milk allergy, soy allergy and/or lactose intolerance;

4. Having a mother suffering from diabetes during pregnancy;

5. Participation in another clinical trial;

6. Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-09-2010
Aantal proefpersonen:	344
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-09-2010
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	NL2413
NTR-old	NTR2521
Ander register	Danone Research BV : Dig.1.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
1) Newly-developed Fermented Infant Formulas, Combining scGOS/lcFOS with Lactofidus, Show Equivalence of Weight Gain in Healthy Infants: A Randomized, Controlled, Double-blind, Multicenter, Intervention Study Vandenplas Y, Hourihane J, Bouritius H, Pennings B, Huet F, EAP 2013

2) A novel infant formula, combining scGOS/lcFOS with a specific fermented infant formula, shows lower incidence of colic in infants at 4 weeks of age compared to control formulas. Yvan Vandenplas, Hetty Bouritius, Thomas Ludwig, Frederic Huet, Jonathan Hourihane, ESPGHAN 2014

3) Associatoin of infantile colic with functional gastrointestinal disorder and symptoms.Vandenplas Y; Ludwig T; van Elburg R; Bouritius H; Huet F ESPGHAN 2015
4)Partly Fermented Infant Formulae With Specific Oligosaccharides Support Adequate Infant Growth and Are Well-Tolerated. Huet F, Abrahamse-Berkeveld M, Tims S, Simeoni U, Beley G, Savagner C, Vandenplas Y, Hourihane JO. J Pediatr Gastroenterol Nutr.2016 Oct;63(4:e43-53