Fermented infant formula with prebiotics study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25687

Source
Nationaal Trial Register

Brief title
FIPS

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

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

Secondary outcome

Anthropometrics other than weight gain, gastrointestinal tolerance, crying, sleeping, stool characteristics, faecal parameters, safety, use of medication and nutritional supplements.

Study description

Background summary

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.

Study objective

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).

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2010
Enrollment:	344
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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

Study results

Summary results

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