# Prebiotic oligosaccharides and fermented formula study.

No registrations found.

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

## Summary

### ID

NL-OMON20626

**Source**
Nationaal Trial Register

**Brief title**
Life

**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**

The incidence, occurrence and severity of gastrointestinal symptoms.

**Secondary outcome**

1. To explore the effect on quality of life and on digestion-related parameters;

2. To investigate adequate growth of the study product groups compared to WHO Child Growth Standards;

3. To describe the data of the breastfed reference group.

# Study description

**Background summary**

In this study an infant formula with prebiotic oligosaccharides and fe rments is compared with infant formula without these compounds. Both study products also have lower protein content as compared to regular infant formula. All infants will be fed ad libitum, either with the study product or with human milk.

The main parameter being studied is gastrointestinal symptoms. Furthermore, quality of life, digestion and growth are studied. The results are compared to a breastfeeding group. In total 200 healthy term infants will be randomised to one of the two study product groups; a further 100 healthy term infants will be included in the breastfeeding reference group.

The infants should have a birth weight of between 2.5 and 4.5 kg, and be no older than 28 days. The infants should not have been fed with infant formula with probiotics or synbiotics prior to participation in the study, have congenital defects or a current illness that could interfere with the study, have a known risk of cow-milk or other allergies, or have a mother suffering from diabetes. The infants will be included in the study until they are 4 months of age.

The intervention period is 15 to 19 weeks, depending on the age of the infant at entry, including a non-interventional follow-up period of two weeks.

The infants need to visit the study site maximally 5 times for assessment of:

1. Length and weight;

2. Incidence, occurrence and severity of gastrointestinal symptoms;

3. Regurgitation;

4. Stool consistency;

5. Sleeping and crying time;

6. Adverse events;

7. Concomitant medication.

Parents will be asked to fill in a diary with information on some of these parameters, and some questionnaires. Furthermore, they will be asked to collect a stool sample 3 times during the study. In between visits there will be a phone call from the site staff.

The study is planned to start Q2 2012, and planned to be completed Q4 2013.

**Study objective**

Adding prebiotics or ferments to infant formula may improve digestive comfort in infants. Therefore, the infant formula tested in this study, combining these ingredients, may contribute to improved digestive comfort. In this study it also has been decided to have a low protein formula (1.8 g/100 kcal), to study growth data and compare the data obtained with the WHO curves to confirm the nutritional safety of this protein/energy ratio in our product (WHO 2006).

**Study design**

Time points of the outcome: V2 (Week 4); V3 (Week 8); V4 (week 13) and V5 (Week 17).

The following measurements will take place:

1. Length and weight;

2. Incidence, occurrence and severity of gastrointestinal symptoms;

3. Regurgitation;

4. Stool consistency;

5. Sleeping and crying time;

6. Adverse events;

7. Concomitant medication.

Parents will be asked to fill in a diary with information on some of these parameters, and some questionnaires.

A stool sample will be collected 3 times during the study.

**Intervention**

Duration of intervention: 13-17 weeks.

Intervention group: Infant formula containing prebiotics and ferments.

Control group: Infant formula without prebiotics and ferments.

A reference group with full breastfeeding will be included.

All infants will be fed ad libitum, either with the study product or with human milk.

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Healthy and term infants (gestational age ≥ 37 and ≤ 42 weeks);

2. Infants who are exclusively formula fed (mothers who have chosen not to breastfeed or mothers who ceased breastfeeding by time of inclusion), or;

3. Infants who are exclusively breastfed (mothers who are willing to breastfed for at least till their infant is 17 weeks of age);

4. Birth weight between 2,5 - 4,5 kg;

5. Age ≤ 28 days (preferably as soon as possible after birth);

6. Written informed consent from parents or legal guardians.

## Exclusion criteria

1. Infants fed with infant formula containing probiotics or synbiotics prior to study entry;

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(i.e. one of the biological parents diagnosed with asthma, hay fever, nasal allergy, eczema, skin allergy, and/or food allergy) ;

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/legal guardian 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): | 01-06-2012 |
| Enrollment: | 300 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 30-05-2012 |
| 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 | NL3308 |
| NTR-old | NTR3455 |
| Other | Danone Research : Dig.1.C/B |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**

The combination of scGOS/lcFOS and fermented infant formula softens stools of infants compared to unfermented infant formula without scGOS/lcFOSscGOS/lcFOS. Herrera AR, Ludwig T, Bouritius H, Rubio RP, Muñoz A, Agosti M, Lista G, Corvaglia LT, Navero JL. J Pediatr Gastroenterol Nutr. 2015 Oct;61(4):516-7