

# The role of pre- and probiotics in infections in term infants (De role van pre- en probiotica in infecties in a terme geboren kinderen)

<b>Submission date</b> 09/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2008	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

VIPP a terme

## Study objectives

Supplementation of infant formula with a combination of pre- and probiotics may protect infants against infectious complications such as diarrhoea and respiratory infections. We speculate that the combination of pre- and probiotics is a better protective than only one of these substances. Supplementation of the combination of pre- and probiotics may reduce the incidence of infections to the same level as human milk-fed infants.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of the Isala Clinics according to article 16 WMO and according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use/Good Clinical Practice (ICH /GCP) criteria on the 8th February 2007 (ref: 06.1178).

## Study design

Double blind placebo-controlled randomised prospective cohort study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Heathy term infants with intercurrent diseases: diarrhoea and respiratory infections

## Interventions

Treatment consists of three types of infant formula:

1. Standard infant formula (frisolac 1) without addition of prebiotics or probiotics
2. Standard infant formula with addition of galacto-oligosaccharides (GOS); 0.8 g/100 ml (Vivinal Domo, The Netherlands. GOS 10 contains: galacto-oligosaccharides 28.5%, lactose 36%, glucose 9.5%, galactose 0.5%, proteins 17.5%, minerals 3.5%, fat 1.5%, moisture 3.0%)
3. Standard infant formula with addition of a mixture of prebiotics (GOS [the same as B]) and a probiotic mixture consisting of lactobacillus casei CRL 431 2 x 100,000/ml and bifidobacterium lactis BB 2 x 100,000/ml (Bioflora Pharma Nord, The Netherlands)

The total duration of treatment is 6 months, faeces samples will be taken at 6 weeks, 3 and 6 months. Questionnaires regarding frequency of diarrhoea, airway infection, and feeding tolerance will be filled in by the parents every 2 weeks during the study period (6 months). All questionnaires (e.g. regarding infections, faecal composition and feeding tolerance) are standardised. An outpatient visit for growth measurements will be held at 3 and 6 months.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Prebiotics, probiotics

### **Primary outcome measure**

1. Frequency, incidence and duration of diarrhoea and respiratory infections, measured during the first 6 months of life and evaluated by the questionnaires
2. Composition of gut flora, evaluated at week 6, 3 months and 6 months of life (during the period infants receive the study feeds)

### **Secondary outcome measures**

1. Growth (head circumference, length and weight), measured in the out-patient clinic at 3 and 6 months
2. Feeding tolerance (pattern of defaecation, consistence of faeces, crying, vomiting, stomach ache), assessed with standardised questions

### **Overall study start date**

01/04/2007

### **Completion date**

01/04/2009

## **Eligibility**

### **Key inclusion criteria**

1. Healthy term infants with a post-menstrual age of 37 - 42 weeks, either sex
2. Birth weight between P10 and P90
3. Informed consent of both parents

### **Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

Formula group: n = 225 (75 in every group). Reference group (human milk ) n = 150.

**Key exclusion criteria**

1. Neonatal sepsis
2. Severe congenital malformations
3. Birth asphyxia (apgar less than six at 5 minutes, and/or umbilical cord pH less than 7.00 and/or necessity of reanimation)
4. Admission to a paediatric ward
5. No Dutch or English speaking parents
6. Antibiotics to the mother during labour
7. Antibiotics to the infant in the first week of life
8. History of allergy with parents or siblings

**Date of first enrolment**

01/04/2007

**Date of final enrolment**

01/04/2009

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Isala Clinics

Zwolle

Netherlands

8025 AB

## **Sponsor information**

**Organisation**

Royal Friesland Foods B.V. (The Netherlands)

**Sponsor details**

c/o Dr R te Biesebeke  
Enhanced Nutrition Specialist Unit  
P.Stuyvesantweg 1  
Leeuwarden  
Netherlands  
8937 AC

**Sponsor type**

Industry

**Website**

<http://www.frieslandfoods.com>

**ROR**

<https://ror.org/025mtxh67>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Royal Friesland Foods B.V. (The Netherlands)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration