

# The role of pre- and probiotics in infections in term infants.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26255

### Source

NTR

### Brief title

HIPPO

### Health condition

Heathy term infants with intercurrent diseases: diarrhoea and respiratory infections.

## Sponsors and support

**Primary sponsor:** Sponsor: Dr R te Biesebeke

Global Development Centre

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Performer: Dr Diny van Zoeren-Grobbe

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**Source(s) of monetary or material Support:** Fund = initiator = sponsor

## Intervention

## Outcome measures

### Primary outcome

- Frequency, incidence and duration of diarrhoea and respiratory infections  
composition of gut flora

### Secondary outcome

- Growth (head circumference, length and weight)  
  
- Feeding tolerance (pattern of defecation, consistence of faeces, crying, vomiting, stomach ache)

## Study description

### Background summary

We speculate that the combination of pre and probiotics is 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.

Supplementation of infant formula with a combination of pre- and probiotics may protect infants against infectious complications such as diarrhoea and respiratory infections.

### Study objective

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 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.

### Study design

1 - Frequency, incidence and duration of diarrhoea and respiratory infections, feeding

2 - The role of pre- and probiotics in infections in term infants. 11-05-2025

tolerance : 2 weekly

2 - Antropometry: t=0, T = 3 and T=6 mths

3 - Fecal samples: T=0, T=3 and T=6 months

### **Intervention**

Supplementation of infant formula with an combination of pre- and probiotics.

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

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

## Exclusion criteria

1. Neonatal sepsis
2. Severe congenital malformations
3. Birth asphyxia (apgar < 6 at 5 minutes, and/or umbilical cord pH < 7.00 and/or necessity of reanimation)
4. Admission to a pediatric 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 sibs

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	04-01-2007
Enrollment:	225
Type:	Anticipated

## Ethics review

Positive opinion

Date: 23-10-2008

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	NL1442
NTR-old	NTR1503
Other	: 06-1178
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

- 1) Effect of supplementation of infant formula with a a combination of pre- and probiotics on incidence and duration of infectious complications in term infants. <br><br>
- 2) Effect of supplementation of of infant formula with a a combination of pre- and probiotics on the composition of gut flora.