# The effects of a prebiotic supplement of fecal consistancy, mineral absorption and gut flora in low birthweight infants.

No registrations found.

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

## Summary

### ID

NL-OMON27890

**Source**
NTR

**Brief title**
POEMA trial

**Health condition**

Gestational age less then 34 weeks
birtheight below 1700 grams.

### Sponsors and support

**Primary sponsor:** friesland coberco diary foods
friesland nutrion research
Pieter Stuyvesantweg 1
8937 AC Leeuwarden
the Netherlands
**Source(s) of monetary or material Support:** none other then sponsor

### Intervention

## Outcome measures

### Primary outcome

1. Number of stools/day;

2. Gutflora;

3. Safety.

### Secondary outcome

Growth (increase in weight per kg per day).

# Study description

### Background summary

Prebiotics, galacto-oligosaccharides, are present in breastfeeding and are responsable for more favourable gutflora, and fecal consistancy compared to regular premature formula fed infants. concerns have been raised, that adding prebiotics to premature formula causing looser stools may disturb fluid balance in premature infants.
We speculate that the latter will not happen since the amount of prebiotics added is less than half present in breastfeeding.

### Study objective

Prebiotics are present in breastfeeding and thusfar not in premture formula, we presume that adding prebiotics to premature formula, will be well tolarated, result in more loose stools compared to regular premature formula and will be responsable for gut flora which is present in breastfed infants.

### Study design

N/A

### Intervention

Adding prebiotics (galacto-oligosaccharides) to premature formula.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Gestational age less then 34 weeks;

2. Birthweight less then 1700 grams.

## Exclusion criteria

1. Congenital defects;

2. Motility disorders of the gut;

3. Necrotising enterocolitis;

4. Medication with effects on gastric motility or intestinal flora (i.e. antibiotics).

# Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-05-2002 |
| Enrollment: | 60 |
| Type: | Actual |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 09-09-2005 |
| 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 | NL277 |

| Register | ID |
| --- | --- |
| NTR-old | NTR315 |
| Other | : N/A |
| ISRCTN | ISRCTN87058658 |

# Study results

**Summary results**
N/A