# The effects of a prebiotic supplement of faecal consistency, mineral absorption and gut flora in low birth weight infants

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
20/12/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	Results
Last Edited	Condition category	Individual participant data
03/07/2009	Pregnancy and Childbirth	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Mrs E. Smit

#### Contact details

Medical Spectrum Twente, P.O. Box 50000 Enschede Netherlands 7500 KA

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

**NTR315** 

# Study information

#### Scientific Title

#### **Acronym**

POEMA trial

#### Study objectives

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

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Received from the local medical ethics committee

#### Study design

Randomised double blind placebo controlled parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

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

Very low birth weight

#### **Interventions**

Adding prebiotics (galacto-oligosaccharides) to premature formula.

# Intervention Type

Supplement

#### Phase

Not Applicable

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

#### Prebiotic (galacto-oligosaccharides) supplementation

#### Primary outcome measure

- 1. Number of stools /day
- 2. Gut flora
- 3. Safety

#### Secondary outcome measures

Growth (increase in weight per kg per day)

#### Overall study start date

01/05/2002

## Completion date

01/05/2006

# Eligibility

#### Key inclusion criteria

- 1. Gestational age less then 34 weeks
- 2. Birth weight less then 1700 grams

#### Participant type(s)

**Patient** 

#### Age group

Child

#### Upper age limit

34 Weeks

#### Sex

Both

### Target number of participants

60

#### Key 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)

#### Date of first enrolment

01/05/2002

#### Date of final enrolment

01/05/2006

# Locations

#### Countries of recruitment

Netherlands

Study participating centre Medical Spectrum Twente, Enschede Netherlands

7500 KA

# Sponsor information

#### Organisation

Friesland Coberco Dairy Foods Holding NV (Netherlands)

#### Sponsor details

Friesland Nutrition Research P.O. Box 226 Leeuwarden Netherlands 8901 MA

#### Sponsor type

Industry

#### **ROR**

https://ror.org/025mtxh67

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Friesland Coberco Dairy Foods Holding NV (Netherlands) - Friesland Nutrition Research

# **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