

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/07/2009	Condition category Pregnancy and Childbirth	<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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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Growth (increase in weight per kg per day)

Completion date

01/05/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

34 weeks

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration