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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 03/07/2009	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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