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Tolerance of probiotics in the neonate

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
NTR313

Study information

Scientific Title

Tolerance for probiotics and its effect on growth and faeces of neonates

Acronym
PINGO (Probiotica in Neonatale Groei en Ontlasting)

Study objectives
Probiotics are tolerated well by infants (age 0 - 3 months) and results in a microbial flora resembling that of breastfed infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from 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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Gut flora and growth parameters

Interventions
All infants receive formula feeding for the first three months, 75 with probiotics (L. casei and B. animalis) and 75 without.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Growth parameters (weight, length and head circumference)

Secondary outcome measures
1. Gut flora (tested with quantitative polymerase chain reaction [PCR])
2. Hours of crying, sleeping, etc
3. Defaecation patterns

Overall study start date
01/11/2004

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Healthy, term neonate
2. Aged less than 7 days
3. Informed consent
4. Parents are fluent in Dutch

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Antibiotics postpartum
2. Congenital malformations, etc

Date of first enrolment
01/11/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

St. Antonius Hospital
Nieuwegein
Netherlands
3430 EM

Sponsor information

Organisation
Friesland Foods (Netherlands)

Sponsor details
Blankenstein 142
Meppel
Netherlands
7943 PE

Sponsor type
Industry

Website
http://www.nl.frieslandcampina.com/

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