ISRCTN78225533 https://doi.org/10.1186/ISRCTN78225533

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

Contact name
Dr Arine M Vlieger

Contact details
St. Antonius Hospital
Department of Pediatrics
P.O. Box 2500
Nieuwegein
Netherlands
3430 EM

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled parallel-group trial

Study type(s)
Treatment

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(s)
Growth parameters (weight, length and head circumference)

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

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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)

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