

Tolerance of probiotics in the neonate

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

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

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