

The role of pre- and probiotics in infections in term infants (De role van pre- en probiotica in infecties in a terme geboren kinderen)

Submission date 09/05/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/09/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 12/09/2008	Condition category Neonatal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

06-1178

Study information

Scientific Title

Acronym

VIPP a terme

Study objectives

Supplementation of infant formula with a combination of pre- and probiotics may protect infants against infectious complications such as diarrhoea and respiratory infections. We speculate that the combination of pre- and probiotics is a better protective than only one of these substances. Supplementation of the combination of pre- and probiotics may reduce the incidence of infections to the same level as human milk-fed infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of the Isala Clinics according to article 16 WMO and according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use/Good Clinical Practice (ICH /GCP) criteria on the 8th February 2007 (ref: 06.1178).

Primary study design

Interventional

Study design

Double blind placebo-controlled randomised prospective cohort study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Healthy term infants with intercurrent diseases: diarrhoea and respiratory infections

Interventions

Treatment consists of three types of infant formula:

1. Standard infant formula (frisolac 1) without addition of prebiotics or probiotics
2. Standard infant formula with addition of galacto-oligosaccharides (GOS); 0.8 g/100 ml (Vivinal Domo, The Netherlands. GOS 10 contains: galacto-oligosaccharides 28.5%, lactose 36%, glucose 9.5%, galactose 0.5%, proteins 17.5%, minerals 3.5%, fat 1.5%, moisture 3.0%)
3. Standard infant formula with addition of a mixture of prebiotics (GOS [the same as B]) and a probiotic mixture consisting of lactobacillus casei CRL 431 2 x 100,000/ml and bifidobacterium lactis BB 2 x 100,000/ml (Bioflora Pharma Nord, The Netherlands)

The total duration of treatment is 6 months, faeces samples will be taken at 6 weeks, 3 and 6 months. Questionnaires regarding frequency of diarrhoea, airway infection, and feeding tolerance will be filled in by the parents every 2 weeks during the study period (6 months). All questionnaires (e.g. regarding infections, faecal composition and feeding tolerance) are standardised. An outpatient visit for growth measurements will be held at 3 and 6 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prebiotics, probiotics

Primary outcome(s)

1. Frequency, incidence and duration of diarrhoea and respiratory infections, measured during the first 6 months of life and evaluated by the questionnaires
2. Composition of gut flora, evaluated at week 6, 3 months and 6 months of life (during the period infants receive the study feeds)

Key secondary outcome(s)

1. Growth (head circumference, length and weight), measured in the out-patient clinic at 3 and 6 months
2. Feeding tolerance (pattern of defaecation, consistence of faeces, crying, vomiting, stomach ache), assessed with standardised questions

Completion date

01/04/2009

Eligibility**Key inclusion criteria**

1. Healthy term infants with a post-menstrual age of 37 - 42 weeks, either sex
2. Birth weight between P10 and P90
3. Informed consent of both parents

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Neonatal sepsis
2. Severe congenital malformations
3. Birth asphyxia (apgar less than six at 5 minutes, and/or umbilical cord pH less than 7.00 and/or necessity of reanimation)
4. Admission to a paediatric ward
5. No Dutch or English speaking parents

6. Antibiotics to the mother during labour
7. Antibiotics to the infant in the first week of life
8. History of allergy with parents or siblings

Date of first enrolment

01/04/2007

Date of final enrolment

01/04/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Isala Clinics

Zwolle

Netherlands

8025 AB

Sponsor information

Organisation

Royal Friesland Foods B.V. (The Netherlands)

ROR

<https://ror.org/025mtxh67>

Funder(s)

Funder type

Industry

Funder Name

Royal Friesland Foods B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration