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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2008	**Overall study status** Completed	
Last Edited 12/09/2008	**Condition category** Neonatal Diseases	

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

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).

Study design
Double blind placebo-controlled randomised prospective cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Heathy 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-oligosaccarides 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 measure
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)

Secondary outcome measures
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

Overall study start date
01/04/2007

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

Age group
Neonate

Sex
Both

Target number of participants
Formula group: n = 225 (75 in every group). Reference group (human milk) n = 150.

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)

Sponsor details

c/o Dr R te Biesebeke
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P.Stuyvesantweg 1
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8937 AC

Sponsor type
Industry

Website
http://www.frieslandfoods.com

ROR
https://ror.org/025mtxh67

Funder(s)

Funder type
Industry

Funder Name
Royal Friesland Foods B.V. (The Netherlands)

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