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Effect of prebiotic or lactoferrin supplementation in formula on the gut flora of preterm infants

Submission date	Recruitment status	[ ] Prospectively registered
09/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/09/2008	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06-1179

Study information

Scientific Title

Acronym
VIPP prematuur

Study objectives
Supplementation of preterm formula with prebiotics or lactoferrin may improve the gut flora of preterm infants by promoting growth of apathogenic bacteria. These supplements may produce a gut flora resembling the gut flora of human milk-fed preterm infants and thereby improve their resistance against infections.

Furthermore lactoferrin reduces the availability and absorption of free iron and may thus reduce oxidative stress both locally in the gut and systemically.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethcis approval received from the Medical Ethical Committee of the Isala Clinics according to article 16 WMO and 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: 06.1179).

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
Gut flora

Interventions
Treatment consists of three types of preterm formula:
1. Standard preterm formula (frisolac prematuur) without addition of prebiotics
2. Standard preterm formula with addition of galacto-oligosaccharides (GOS); 0.8 g/100 ml (Vivinal Domo, The Netherlands. GOS 10 containing: 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 preterm formula with addition of dairy lactoferrin 1 mg/100 ml (Vivinal Domo, The Netherlands, containing lactoferrin 90 %, protein 97%, moisture 1.5%, minerals 1.5 %)

The therapy wil be started in the first week of life and therapy will be continued until 6 weeks after the start of full enteral feeds. Blood will be drawn at day 1, day 7, day of full enteral feeds and week 6 after establishment of full enteral feeds. Follow up wil be done at the age of 1 year corrected age.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prebiotic, lactoferrin

Primary outcome measure
1. Composition of gut flora, evaluated at 6 weeks of full enteral feeds (at the end of the study feeding)
2. Incidence of infections, measured at 6 weeks of full enteral feeds
3. Oxidative stress and iron status, measured at 6 weeks of full enteral feeds

Secondary outcome measures
1. Growth (head circumference, length, weight), measured at 6 weeks of full enteral feeds
2. Feeding tolerance (composition of faeces, crying pattern, discomfort, vomiting), measured at 6 weeks of full enteral feeds
3. Psychomotor development, taken at 1 year of age

Overall study start date
01/04/2007

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Preterm infants: gestational age 26+0 to 35+6 weeks, either sex
2. Admitted to the Neonatal Intensive Care Unit (NICU) or High Care Unit of the hospital

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Preterm formula group: n = 60 (20 in each group). Human milk group: n = 20.

Key exclusion criteria
1. Birth weight less than 600 g
2. Life-threatening congenital malformations
3. No Dutch or English speaking parents
4. History of allergy in 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
Enhanced Nutrition Specialist Unit
P. Stuyvesantweg 1
Leeuwarden
Netherlands
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