

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

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
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Diny van Zoeren-Grobbe

Contact details

Isala Clinics
Neonatal Unit
Dr. Van Heesweg 2
Zwolle
Netherlands
8025 AB
+31 (0)38 424 7073
d.van.zoeren@isala.nl

Additional identifiers

Protocol serial number

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)

Ethics 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).

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

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-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 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 will 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 will 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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