

The Preterm Prebiotic Study

Submission date 20/08/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2013	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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
NRG / II DbCoRPMc / PT EL 01

Study information

Scientific Title

Study objectives

Supplementation of a preterm formula with 0.8 g galacto-oligosaccharides (GOS)/fructo-oligosaccharides (FOS) mixture per dl (ratio: 9:1) will result in an improvement in enteral tolerance.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neonatal nutritional supplementation

Interventions

Infants randomised to one of two groups receiving either Nutriprem A or B, one without and one with 0.8 g GOS/FOS oligosaccharides /dl, to make up any shortfall in their own mothers milk or as sole diet if maternal milk is unavailable.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Galacto-oligosaccharides (GOS)/fructo-oligosaccharides (FOS)

Primary outcome(s)

1. Number of days from birth to reach a total (sole formula or formula with breast milk) daily enteral intake of 150 ml/kg
2. Number of days between birth and 28 days that a total (sole formula or formula with breast milk) daily enteral intake of at least 150 ml/kg is tolerated

Key secondary outcome(s)

1. Gain in weight, length and head circumference
2. Faecal flora
3. Faecal calprotectin
4. Faecal characteristics
5. Gastrointestinal tolerance
6. Fluid balance
7. Necrotising enterocolitis
8. Bloodstream infection

Completion date

30/06/2007

Eligibility

Key inclusion criteria

Preterm infants, appropriately grown for gestational age, with a gestational age $\leq 32 + 6$ weeks (days), whose mothers agree to the use of formula if they are unable to or do not wish to breast feed or are not able to provide sufficient breast milk

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. More than 72 hours exclusive parenteral nutrition
2. Immediately life-threatening congenital abnormality
3. Any condition requiring major surgery

Date of first enrolment

01/10/2005

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Imperial College London

London

United Kingdom

SW10 9NH

Sponsor information

Organisation

Milupa GmbH, Numico Research (Germany)

ROR

<https://ror.org/00aj77a24>

Funder(s)

Funder type

Industry

Funder Name

Numico Research (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010		Yes	No