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The Preterm Prebiotic Study

Submission date 20/08/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2005	**Overall study status** Completed	
Last Edited 01/02/2013	**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
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-oligosacharides (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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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-oligosacharides (FOS)

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/10/2005

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Preterm infants, appropriately grown for gestational age, with a gestational age ≤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

Age group
Neonate

Sex
Both

Target number of participants
160

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
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Milupa GmbH, Numico Research (Germany)

Sponsor details
Bahnstrasse 14-30
Friedrichsdorf
Germany
61381

Sponsor type
Industry

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research (Germany)

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

Study outputs

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