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A prospective double-blind randomised controlled trial of the effect of a prebiotic mixture of bifidogenic oligosaccharides on enteral tolerance in preterm infants

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
01/10/2014

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
N0112173765

Study information

Scientific Title

Study objectives
The aim of the study is to determine if supplementation of preterm infant milk formula with 0.8 g GOS/FOS mixture/dl (galacto-oligosaccharides (GOS) and fructo-oligosaccharides (FOS) are prebiotic bifidogenic oligosaccharides) will lead to an improvement in enteral tolerance and a more rapid establishment of milk feeds.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective double-blind 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 Diseases

Interventions
Suitable babies less that 32+6 weeks gestation who are also of appropriate birth weight for gestational age will be identified by neonatal unit staff. Parent will be approached and explanation of study given by the first 24 hours prior to starting of feeds. Formula milk will only be used if there is a shortfall in the volume available of their own mother's milk, or as sole diet if maternal milk is unavailable. Randomisation will be performed to either a standard preterm formula or to one with GOS/FOS these will be labelled either A or labelled formula. Enteral feeding will be commenced within 24 hours of birth. Measurements will be taken on four/five occasions:
1. Day 1: commencement of enteral feed

2. Day 2: the first day of enteral feeding at a volume of 150 ml/kg
3. Day 3: day 28 of post-natal life
4. Day 4: the day when 37 weeks of gestational age is reached
5. Day 5: the day when 40 weeks of gestation age would have been reached, or the day of discharge, whichever occurs earlier

Information collected on the Case Report Form (CRF) will be logged with the trial administrator who will check for completeness. The principal investigator will coordinate CRFs and trial database at Imperial. Stool samples will be collected from the nappy on day 1 and 3.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Galacto-oligosaccharides (GOS) and fructo-oligosaccharides (FOS) are prebiotic bifidogenic oligosaccharides.

Primary outcome measure
1. Number of days from birth to establish 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 (change in Z score between birth and 40 weeks postmenstrual age)
2. Faecal flora (colony forming units/g stool of Bifidus sp., Lactobacilli sp., and pathogenic micro-organisms)
3. Faecal calprotectin
4. Stool characteristics
5. Gastrointestinal tolerance
6. Fluid balance (the number of days between trial entry and 28 days where serum sodium exceeds 148 mmol/l or serum creatinine exceeds 150 micromol/l)
7. Proven necrotising enterocolitis according to predefined diagnostic criteria
8. Proven bloodstream infection according to predefined diagnostic criteria

Overall study start date
02/12/2005

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Written informed parental consent
2. Preterm infants, appropriately grown for gestational age (Child Growth Foundation UK

reference), with a gestational age of 32 weeks, whose mother agree to the use of formula if they are unable to or do not wish to breastfeed or are not able to provide sufficient breast milk

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
4

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
02/12/2005

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Epsom and St Helier NHS Trust
Carshalton
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SM5 1AA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

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