

# The Preterm Prebiotic Study

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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-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

**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-oligosaccharides (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  $\leq 32 + 6$  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

### **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?
<a href="#">Results article</a>	results	01/11/2010		Yes	No