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Exploratory randomised double-blind controlled trial of breast milk fortifier with and without long chain polyunsaturated fatty acid (LCPUFA) supplementation on body composition in preterm infants

Submission date 06/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/08/2007	**Condition category** Neonatal Diseases	[_] 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
N/A

Study information

Scientific Title

Study objectives
Breast milk fortifier containing LCPUFA has a measurable effect upon body composition at term when compared with non-LCPUFA supplemented fortifier

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Preterm infants

Interventions
Infants will receive maternal +/- donor breast milk; should breast milk fortifier be indicated in accordance with normal clinical practice, infants will be randomised to receive standard fortifier or LCPUFA supplemented fortifier.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Body composition at age term-equivalent

Secondary outcome measures
Growth, metabolic profile, intrahepatocellular lipid content, brain growth and development, neurological examination

Overall study start date
01/08/2005

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Infants born at or below 32 weeks gestational age

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
120 of whom 42 will be randomised

Key exclusion criteria
1. Major congenital abnormality

2. Mother does not wish to provide breast milk or to use donor milk
3. Baby requires gastrointestinal surgery

Date of first enrolment
01/08/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

Germany

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
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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