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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

Registration date
13/09/2005

Overall study status
Completed

Last Edited
30/08/2007

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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Body composition at age term-equivalent

Key secondary outcome(s))
Growth, metabolic profile, intrahepatocellular lipid content, brain growth and development, neurological examination

Completion date
30/06/2006

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

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
United Kingdom

England

Germany

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