

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

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| Submission date 06/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 13/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 30/08/2007 | Condition category Neonatal Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Neena Modi

Contact details
Imperial College London
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Additional identifiers

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