ISRCTN13923832 https://doi.org/10.1186/ISRCTN13923832

Pilot study to compare preterm infant nutrition with individually supplemented with standard supplemented breast milk

Submission date
29/01/2013

Recruitment status
No longer recruiting

Registration date
01/03/2018

Overall study status
Completed

Last Edited
08/03/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gastrointestinal (digestive system) complications are reduced in preterm infants if they are fed with breast milk. However, breast milk must be fortified because the nutrient content is not enough for rapidly growing preterm infants. Furthermore, the nutrient content of breast milk can vary. The aim of this study is find out whether supplementation using measurements of actual nutrient content is better than standard supplementation.

Who can participate?
Preterm infants (gestational age 24 - 32 weeks) with a birth weight of 400 - 1499 g, receiving enteral (tube) feeds for at least 2 – 4 days

What does the study involve?
Infants are randomly allocate to receive either breast milk feeds supplemented with fortifiers calculated according to measured natural nutrient content, to provide nutrients according to the ESPGHAN recommendations, or breast milk supplemented with the standard amounts of fortifiers. Weight gain, bone growth, adipose (fat) tissue and blood amino acids are all measured over 8 weeks.

What are the possible benefits and risks of participating?
All infants receive extensive nutritional observation and evaluation. Infants on individualized supplementation may have faster weight gain because the varying nutrient contents of breast milk batches are compensated for. Breast milk fortification is standard in the care of preterm infants. Therefore, there are no additional risks from participation in this study.

Where is the study run from?
The Children’s Hospital of the University of Leipzig and the City Hospital Harlaching (Germany)

When is the study starting and how long is it expected to run for?
March 2013 to June 2014

Who is funding the study?
Milupa (Germany)

Who is the main contact?
1. Prof. Dr. med. Ulrich H. Thome
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2. Prof. Dr. Walter Mihatsch

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18

Study information

Scientific Title
Pilot study to compare preterm infant nutrition with individually supplemented with standard supplemented breast milk

Acronym
PPN

Study objectives
Supplementation of breast milk based on milk analysis results in better weight gain than standard supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission an der Medizinischen Fakultät der Universität Leipzig, 21/03/2013, ref: 082-13-11032013

Study design
Randomized multi-center trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Feeding preterm infants

Interventions
Infants are randomized to receive either breast milk feeds supplemented with fortifiers calculated according to measured natural nutrient content, to provide nutrients according to the ESPGHAN recommendations, or breast milk supplemented with standard amounts of fortifiers.

Intervention Type
Supplement

Primary outcome measure
Weight gain measured daily

Secondary outcome measures
1. Linear growth: 2-weekly measurement (week 0, 2, 4, 6, 8)
2. Head circumference: 2-weekly measurement (week 0, 2, 4, 6, 8)
3. Leg growth: 2-weekly measurement (week 0, 2, 4, 6, 8)
4. Skin fold thickness: 2-weekly measurement (week 0, 2, 4, 6, 8)
5. Body composition at 36 (35 5/7 36 6/7) weeks corrected age
5.1. Analysis of body composition by air displacement, using the Pea Pod (CosmedR) (Munich center)
5.2. Analysis of body composition by bioimpedance analysis (Leipzig center).
6. Serum amino acid profile: measured at weeks 2, 4, 7
7. Bronchopulmonary dysplasia according to the HICHD consensus definition
8. Neurodevelopmental follow-up according to Bayley- 2 scales of infant development at 18-24 months corrected age

Overall study start date
01/03/2013

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Preterm infants < 1500 g birthweight receiving at least 100 ml/kg enteral feeds
2. Male and female premature infants with a gestational age of 24 - 32 weeks (24 0/7 - 31 6/7)

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Abdominal surgery
2. Severe malformations

Date of first enrolment
21/06/2013

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
Germany

Study participating centre
Children’s Hospital of the University of Leipzig
Department of Neonatalogy
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Sponsor information

Organisation
University of Leipzig

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Sponsor type
University/education

ROR
https://ror.org/03s7gtk40

Funder(s)

Funder type
Industry

Funder Name
Milupa AG

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in October 2018.

Intention to publish date
01/10/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date