ISRCTN55092738 https://doi.org/10.1186/ISRCTN55092738

Re-feeding of children with severe acute malnutrition

Submission date	Recruitment status
24/08/2015	No longer recruiting
Registration date	**Overall study status**
02/09/2015	Completed
Last Edited	**Condition category**
20/12/2019	Nutritional, Metabolic, Endocrine

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Severe acute malnutrition (SAM) is defined by the World Health Organisation (WHO) as a very low weight for height, an appearance of wasting away (wasting), or by the presence of nutritional oedema (swelling caused by a build-up of excess fluid in the body). When people are malnourished, the body's metabolism adapts to the lack of nutrients in order to survive, and levels of vitamins and minerals in the body go down. When starving people are re-fed, the body uses more of a mineral called phosphate, as this is needed for turning sugars in the diet into energy. If they are given diets with too much energy too soon then levels of phosphate in the body can become dangerously low as they are used up (re-feeding hypophosphataemia), which can be seriously damaging to health. Special diets have now been introduced which are fortified with phosphates in order to try to prevent re-feeding hypophosphataemia, but the effects of this have not been fully investigated. This study aims to monitor the amount of phosphorus in the blood plasma (P-phosphate) in children being treated for SAM during the re-feeding programme.

Who can participate?
Children admitted to Mwanamugimu Nutrition Unit (Uganda) with signs of SAM.

What does the study involve?
Children who are receiving treatment as an in-patient for SAM are given a therapeutic milk diet. The children are started on Formula 75 (F-75), which includes 75 calories per 100 ml. The F-75 therapeutic milk has been designed to meet the child's needs without overwhelming the body's systems at the start of treatment. The children are then moved onto Formula 100 (F-100) which contains 100 calories per 100 ml. The amount of P-phosphate is measured on admission, at the second day of treatment, at the start of the F-100 treatment, two days later and then at discharge.

What are the possible benefits and risks of participating?
The main benefit of participating in the study is the improved care provided. There are no risks of participating in the study.

Where is the study run from?
Mwanamugimu Nutrition Unit (Uganda)

When is the study starting and how long is it expected to run for?
October 2012 to May 2013

Who is funding the study?
1. University of Copenhagen (Denmark)
2. Augustinus Fonden (Denmark)
3. Lundbeckfonden (Denmark)
4. Brødrene Hartmanns Foundation (Denmark)
5. Arvid Nielsens Foundation (Denmark)
6. Axel Muusfeldts Foundation (Denmark)
7. Aase and Einar Danielsens Foundation (Denmark)
8. Torkild Steenbecks Scholarship (Denmark)

Who is the main contact?
Professor Henrik Friis

Contact information

Type(s)
Scientific

Contact name
Prof Henrik Friis

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
N/A

Study information

Scientific Title

Re-feeding of children hospitalized with severe acute malnutrition: an observational study from Mwanamugimu Nutrition Unit, Uganda

Acronym
FeedSAM

Study hypothesis
The underlying study hypothesis is that children with severe acute malnutrition (SAM) have derangement of phosphorus and other electrolytes, and that these are not adequately corrected by current treatment, and hence delay or prevent recovery of nutritional status and essential body functions.

Primary objective: To assess changes in serum phosphate during treatment of children with SAM with therapeutic milk.
Secondary objectives: To assess changes in and/or predictors of anthropometry, clinical characteristics, child development and physical activity, blood essential fatty acids, immune factors, gut permeability and flora, heart function, and mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee Makerere University (Uganda), 08/08/2012, ref: 2012-134
2. The National Committee on Health and Research Ethics (Denmark), 20/08/2012, ref: 1208653

Study design
Single-centre observational cohort study with nested cross-sectional study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Severe acute malnutrition (SAM) in children

Interventions
There was no experimental intervention. All study participants received in-patient treatment for complicated severe acute malnutrition according to standard protocols based on international guidelines. Uganda follows the approach stated in the Integrated Management for Acute

Malnutrition. The treatment is based on therapeutic milk diets (F-75 and F-100) to children hospitalized with SAM, and treating medical complications. A child is considered to have SAM if it has either weight for height (W/H) below the -3 standard deviations (SD) or mid upper arm circumference (MUAC) below the cut-off points for SAM or pitting oedema developing from both feet. In accordance with treatment guidelines, the duration of treatment with F-75 and F-100, and hence the follow-up time points, depended on the treatment response.

Intervention Type
Other

Primary outcome measure
Plasma phosphate was measured at five time points: on admission, the second day of treatment, the start of the transition to F-100, day two of transition and at discharge.

Secondary outcome measures
1.Blood essential fatty acids at admission, transition, discharge, 8 weeks, 16 weeks
2. Physical activity using accelerometers at discharge
3. Child development using the Malawi Development assessment tool at admission, transition, discharge, 8 weeks, 16 weeks
4. Thymus size using ultrasound at admission, discharge and week 8)
5. T-cell subsets and cytokines using flow cytometry at admission and discharge
6. Gut permeability (LM-test) at admission and discharge
7. Gut flora and pathogens at admission and discharge
8. Myocardial function and biomarkers at admission and discharge
9. Mortality during admission

Overall study start date
01/10/2012

Overall study end date
01/05/2013

Eligibility

Participant inclusion criteria
1. Children between 6 - 59 months of age
2. Admitted to Mwanamugimu Nutrition Unit paediatric wards with either:
2.1 Weight for height (W/H) below the -3 standard deviations (SD) and mid upper arm circumference (MUAC) below the cut-off points for SAM
2.2. Pitting oedema developing from both feet
3. Living near the study centre

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
120

Total final enrolment
120

Participant exclusion criteria
1. Children with shock, severe respiratory difficulty or significant bleeding at the time of admission
2. Weight below 4.5 kg at admission
3. Very severe anaemia

Recruitment start date
10/10/2012

Recruitment end date
21/02/2013

Locations

Countries of recruitment
Uganda

Study participating centre
Mwanamugimu Nutrition Unit
Department of Paediatrics and Child Health
Kampala
Uganda
-

Sponsor information

Organisation
University of Copenhagen (Denmark)

Sponsor details
Nørregade 10
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Sponsor type
University/education

Website
http://www.ku.dk/english/

ROR
https://ror.org/035b05819

Funder(s)

Funder type
University/education

Funder Name
Københavns Universitet

Alternative Name(s)
university_of_copenhagen, Københavns Universitet - University of Copenhagen, University of Copenhagen (UCPH), Copenhagen University, Københavns Universitet – Københavns Universitet, University of Copenhagen (KU), Denmark, Københavns Universitet – University of Copenaghen (UCPH), koebenhavns_uni, Københavns Uni, University of Copenhagen, KU, UCPH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Denmark

Funder Name
Augustinus Fonden

Alternative Name(s)
Augustinus Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Funder Name
Lundbeckfonden

Alternative Name(s)
Lundbeckfonden

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Denmark

Funder Name
Brødrene Hartmanns Foundation

Funder Name
Arvid Nielsens Foundation

Funder Name
Axel Muusfeldts Foundation

Funder Name
Aase and Einar Danielsens Foundation

Funder Name
Torkild Steenbecks Scholarship

Results and Publications

Publication and dissemination plan

1. Changes in plasma phosphate during in-patient treatment of children with severe acute malnutrition: an observational study . Namusoke H, Hother AL, Rytter MJH, Kæstel P, Babirekere-Iriso E, Fabiansen C, Girma T, Ritz C, Michaelsen KF, Briend A, Friis H. Tentative publication date: November 1, 2015
2. Essential fatty acid composition and correlates in children with severe acute malnutrition. Babirekere-Iriso E, Lauritzen L, Mortensen CG, Rytter MJH, Mupere E, Namusoke H, Michaelsen KF, Briend A, Stark KD, Metherel AH, Friis H. Tentative publication date: January 1, 2016
3. Gut microbiota in children hospitalized with oedematous and non-oedematous severe acute malnutrition in Uganda. Kristensen KHS; Wiese M; Rytter MJH; Özcam M; Hansen LH; Namusoke H; Friis H; Nielsen DS . Tentative publication date: February 1, 2016
Correlates of thymus size and changes during treatment of children with severe acute malnutrition: a cohort study. Tentative publication date: March 1, 2016
4. Risk factors for death in children during in-hospital treatment for severe acute malnutrition. Tentative publication date: April 1, 2016
5. Gut pathogens and their clinical correlates in children with severe acute malnutrition. Tentative publication date: April 1, 2016
6. Physical activity status at discharge among children admitted with severe acute malnutrition. Tentative publication date: April 1, 2016
7. Lymphocyte subsets in children with oedematous and non-oedematous severe acute malnutrition. Tentative publication date: October 1, 2016
8. Cytokine patterns and skin symptoms in children with severe acute malnutrition. Tentative publication date: October 1, 2016
9. Heart function in children with severe acute malnutrition. Tentative publication date: October 1, 2016

Intention to publish date

01/11/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	14/03/2017	20/12/2019	Yes	No