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Evaluation of three standard dietary regimes in the treatment of severe malnutrition

Submission date
03/01/2013

Recruitment status
No longer recruiting

Registration date
14/01/2013

Overall study status
Completed

Last Edited
27/03/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Malnutrition is a major cause of death in young children. Even with treatment, risk of death for those needing hospital admission is high. This study aims to compare three diets that are used to treat hospitalized children suffering from Severe Acute Malnutrition (SAM). These are: F100 milk; Ready-to-Use Therapeutic Food (RUTF); F75 milk plus RUTF. Despite all being commonly used during the second, or so called transition, phase in the management of children with SAM, the evidence base for their effectiveness is thin. We will look at their effect on gut function, a major factor determining treatment success. Results of this study will thus provide essential information which can be used to inform national and international policy on SAM.

Who can participate?
All children with SAM [diagnosed according to World Health Organization (WHO) criteria]: low weight-for-height and/or low mid-upper arm circumference and/or nutritional swelling) aged 6-60 months who are admitted for SAM treatment will be eligible to take part. This includes both HIV positive and HIV negative children. Children who are readmissions within the past year or who are already on anti-retroviral-therapy (HIV drug therapy) will be excluded as will severely ill /unstable children (e.g. those presenting with severe anaemia or severe neurological symptoms).

What does the study involve?
When study participants enter the transition phase of treatment they will randomly be assigned to receive one of the three diets 9 F100 milk; Ready-to-Use Therapeutic Food (RUTF); F75 milk plus RUTF) being tested. Blood, stool and urine samples will be taken on three occasions; on admission, just before transition phase and three days into transition phase. Participants will also be reviewed clinically twice a day, paying specific attention to amount of diarrhoea and vomiting. Samples will be shipped to the Netherlands where they will be analysed. Results of the analysis will give information on the effectiveness of the different treatments, specifically looking at how carbohydrates are absorbed in the gut.

What are the possible benefits and risks of participating?
Benefits for participants include special care by the study team and the opportunity for guardians to learn more about their childs condition. Since all three diets are already in common use in various settings, the proposed study protocol poses no major risks for the subjects. All

study children will receive routine care as prescribed by Malawi national guidelines (which are consistent with best practice internationally). Aside from the therapeutic diets, this includes routine antibiotics and other clinical treatments as needed. Mild discomfort and minimal bleeding may occur with the blood sample taking. For the urine sample, a urine bag will be attached on the skin, only if this skin is intact, to prevent local irritation. Benefits for participants include special care by the study team and the opportunity for guardians to learn more about their childs condition.

Where is the study run from?
Study will run from Moyo Ward, which is the specialist Malnutrition Ward at the Paediatrics department at Queen Elizabeth Central Hospital, Blantyre, Malawi.

When is the study starting and how long is it expected to run for?
The study will start beginning of January 2013 and will run until we have included the set amount of participants (108); this is expected to be three to four months. Participants will be enrolled from admission and during the full period of transition phase.

Who is funding the study?
Funding will come from internal sources of the Laboratory of Paediatrics, University Medical Center Groningen, the Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P005/11/1086

Study information

Scientific Title
Evaluation of three standard dietary regimes in the treatment of Severe Malnutrition - a randomised control trial: the TranSAM study

Acronym
TranSAM

Study objectives
Given at the transition phase of inpatient treatment for complicated severe acute malnutrition (SAM), a diet of F75 milk + Ready-to-Use Therapeutic Food (RUTF) causes increased intestinal nutrient (specifically carbohydrate) losses which lead to more diarrhoea, malabsorption and clinical compromise than when children are on transition diets of RUTF alone or F100 milk alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medicine Research and Ethics Committee, Malawi (COMREC), 07/12/2012, ref: P005 /11/1086

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Severe Acute Malnutrition

Interventions
Patients will begin the study once they achieve standardised criteria to move from stabilisation or phase 1 to the transition phase, according to the WHO current guidelines.
The three therapeutic diets to be tested during the transition phase are:

1. A High Energy Therapeutic Regime based on F100 milk: in an iso-volumetric amount to F75 phase 1 milk
2. A High Energy Therapeutic Regime of RUTF supplemented with F75 milk. Caregivers should start a feed by giving ready-to-use therapeutic foods as much as is tolerated by the child (up to a maximum of 135 kcal/kg/d) and then follow by giving F75 - to ensure a minimum intake of 100 kcal/kg/d. The amount of ready-to-use therapeutic foods should increase over 2-3 days until the full requirement of ready-to-use therapeutic foods is taken by the child. F75 should then be stopped.
3. A High Energy Therapeutic Regime of RUTF only. Caregivers should start a feed by giving ready-to-use therapeutic foods as much as is tolerated by the child (up to a maximum of 135 kcal /kg/d) but do so with water and not routinely follow with F75. The amount of ready-to-use therapeutic foods should increase over 2-3 days until the full requirement of ready-to-use therapeutic foods is taken by the child.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Fecal pH
2. Electrolyte disturbances
3. Recovery rate expressed in incremental weight/kg body weight/per day

Patients will be clinically assessed twice a day for the whole duration of the study (e.g. weight, clinical signs).

Secondary outcome measures
1. Morbidity (principally, the rate of carer-reported diarrhoea and severe diarrhoea)
2. Urinary and plasma 8-hydroxydeoxyguanosine
3. Plasma citrulline concentrations
4. Fecal excretion of elastase and alpha 1-antitrypsin
5. Analysis of fecal microbiota

There are three sample moments (feaces, plasma, urine): on admission onto the ward (baseline), just before transition phase (2) and on the 3rd day in transition phase (3).

Overall study start date
07/01/2013

Completion date
07/04/2013

Eligibility

Key inclusion criteria
1. Children between 6-60 months with severe acute malnutrition (World Health Organisation [WHO] criteria: less than -3 Z-score and/or, Mid-Upper Arm Circumference (MUAC) less than

115mm and/or oedema) admitted to Malnutrition Ward, Queen Elizabeth Central Hospital, Blantyre, Malawi
2. Both Human immunodeficiency virus (HIV) positive and negative children will be included

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
108, of which 54 HIV positive and 54 HIV negative

Key exclusion criteria
1. Severely malnourished Human immunodeficiency virus (HIV) infected children who are MOYO [(meaning 'life' in the local Chichewa language) is the name of the malnutrition ward where the study takes place] readmissions within the past year
2. HIV positive children already on anti-retroviral therapy
2. Children presenting with a packed cell volume (PCV) of less than 15%
3. Children with severe haemodynamic instability or severe neurological symptoms / disability
4.Children whose HIV status is unknown due to their carer declining the routinely offered test

Date of first enrolment
07/01/2013

Date of final enrolment
07/04/2013

Locations

Countries of recruitment
Malawi

Study participating centre
Queen Elizabeth Central Hospital
Blantyre
Malawi
Private Box 360

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016		Yes	No
Results article	results	26/04/2017		Yes	No
Results article	results	01/04/2018		Yes	No