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Combined protocol for acute malnutrition study (ComPAS)

Submission date
18/01/2017

Recruitment status
No longer recruiting

Registration date
16/03/2017

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English Summary
Background and study aims
Acute malnutrition in children under 5 is defined by being too thin for a given height and/or having the left arm circumference less than a given threshold (i.e. measuring how fat or thin the mid upper arm circumference (MUAC) is), and/or having swollen feet (malnutrition oedema). It affects 19 million children under five at any point in time, and can result in death if left untreated. Currently, children can receive treatment for uncomplicated acute malnutrition through outpatient treatment programs. Severe cases are treated through an Outpatient Therapeutic Program (OTP) where children receive routine medical care and a take-home ration of ready-to-use therapeutic food known as plumpy'nut once per week, whereas moderate cases are treated through Supplementary Feeding Programs (SFP) where children receive a take-home ration of ready-to-use supplementary known as plumpy'sup food every two weeks. Ideally, severe cases eventually 'graduate' to moderate status. Still this means that children who start as severely malnourished must attend 2 different treatment programs in order to recover. Also, when resources are limited, OTPs are prioritised, leaving moderately malnourished children no option for treatment until they deteriorate into severe status. This study is aiming to simplify and unify the treatment of uncomplicated severe and moderate acute malnutrition for children 6-59 months into one program. The aim of this study is to investigate the effectiveness of treating acute malnutrition using this combined program.

Who can participate?
Children aged 6-59 months old who have been diagnosed with acute malnutrition.

What does the study involve?
Participating health facilities are randomly allocated to one of two groups. Children seeking treatment at sites in the first group are treated using the combined program. This involves a simplified protocol of admission based on mid upper arm circumference (MUAC), case management and treatment based on a reduced dosage of RUTF plumpy'nut until they are discharged from hospital. Children seeking treatment at sites in the second group are treated using the standard protocol. This involves admission, case management and treatment of severe acute malnutrition using plumpy'nut or moderate acute malnutrition using plumpy'sup within

the traditional OTP and SFP structures until they are discharged from hospital. Throughout the study, participants in both groups are monitored to find out whether they recover, how long they are in hospital for and how much weight they put on each day.

What are the possible benefits and risks of participating?
All children will benefit from receiving treatment for malnutrition. There is a risk that children may not gain a lot of weight, if any at all. They may be suffering from other health problems like fever, diarrhea, cough, etc. which are all danger signs requiring them to be admitted to hospital.

Where is the study run from?
Health facilities in Nairobi County (Kenya) and health facilities in Aweil East County (South Sudan)

When is the study starting and how long is it expected to run for?
January 2017 to June 2018

Who is funding the study?
1. Children's Investment Fund Foundation (UK)
2. United States Agency for International Development/Office of Disaster Assistance (USA)

Who is the main contact?
Ms Jeanette Bailey
jeanette.bailey@rescue.org

Contact information

Type(s)
Public

Contact name
Ms Jeanette Bailey

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Combined Protocol for Acute Malnutrition Study (ComPAS) - effectiveness of a combined and simplified protocol for the treatment of acute malnutrition: a prospective, multi-center cluster-randomized controlled non-inferiority trial in Kenya and South Sudan

Acronym
ComPAS

Study hypothesis
1. The treatment of acute malnutrition using the Combined Protocol will be as effective as the standard protocol at recovering children from malnutrition as indicated by program exit status, length of stay, and average weekly weight and MUAC gain
2. Coverage of SAM and MAM treatment will increase under a Combined Protocol by improving early detection of MAM and preventing deterioration into SAM, and by improving program coherence and reducing loss during the transition from OTP to SFP

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine, 28/11/2016, ref: 11826
2. Kenya Medical Research Institute, 5/1/2017, ref: 551
3. Internal Review Board Ministry of Health Government of South Sudan, 21/11/2016

Study design
Cluster-randomized controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Condition
Non-complicated acute malnutrition among children 6-59 months

Interventions

Current interventions as of 01/04/2019:
The intervention tested involves the nutritional treatment of malnourished children age 6-59 months with ready-to use therapeutic foods in Kenya and South Sudan. The unit of randomization will be health facilities stratified by country and then randomly assigned to the control or intervention group. The control arm of the study will adhere to national protocols for the admission, case management and treatment of severe acute malnutrition using RUTF known as plumpy'nut or moderate acute malnutrition using RUSF known as plumpy'sup within the traditional OTP and SFP structures. The intervention arm will follow a combined, simplified protocol for the admission of acutely malnourished children based on mid upper arm circumference (MUAC), case management and treatment based on a reduced dosage of RUTF plumpy'nut. This will continue until discharge. The basic medical treatment of the children admitted with MUAC <115mm and/or bipedal oedema (+/++) on admission and/or weight for height z-score <-3 will be the same between the 2 groups and will follow the recommendations for the management of severe acute malnutrition as per the national protocols in Kenya and South Sudan. The nutritional treatment dosage scheme for the 2 groups is described below.

Control arm:
OTP admission - plumpy'nut RUTF 200kcal/kg/day; received weekly
SFP admission - plumpy'sup RUSF 500 kcal/day; received bi-weekly

Intervention arm:
<115mm and/or oedema (+/++) - two 92g sachets RUTF/day (1000 kcal/day); received weekly
115-<125mm – one 92g sachet RUTF/day (500 kcal/day); received bi-weekly

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Control arm:
OTP admission - plumpy'nut RUTF 200kcal/kg/day; received weekly
SFP admission - plumpy'sup RUSF 500 kcal/day; received bi-weekly

Intervention arm:
<115mm and/or oedema (+) - two 92g sachets RUTF/day (1000 kcal/day); received weekly
115-<125mm – one 92g sachet RUTF/day (500 kcal/day); received bi-weekly

Intervention Type
Other

Primary outcome measure

Recovery from acute malnutrition, defined as two consecutive measurements with a MUAC ≥125mm and no oedema, is assessed by reviewing patient records at end of treatment.

Secondary outcome measures
Current secondary outcome measures as of 02/04/2019:
1. Coverage, defined as % of children eligible for treatment (MUAC<125mm) who receive it, is measured using a SQUEAC survey at the end of the research enrolment period
2. Program default, defined by 3 consecutive missed visits in South Sudan or 3 consecutive missed visits in Kenya, is measured by reviewing patient records monthly for the duration of the
3. Program death rate is measured by reviewing patient records monthly for the duration of the
4. Length of stay in treatment is measured by reviewing patient records to determine the duration of treatment (days) until recover), at end of treatment
5. Average daily weight gain (g/kg/day) is measured by reviewing patient records at end of treatment
6. Average daily MUAC gain (mm/day) is measured by reviewing patient records at end of treatment

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6. Average daily MUAC gain (mm/day) is measured by reviewing patient records at end of treatment

Overall study start date
01/01/2017

Overall study end date
31/08/2018

Eligibility

Participant inclusion criteria
Current participant inclusion criteria as of 01/04/2019:
1. Children aged 6 to 59 months
2. Diagnosed with uncomplicated acute malnutrition and eligible for CMAM treatment, defined as <125mm MUAC and/or bilateral pitting oedema (+/++) in the intervention arm or <125mm MUAC and/or bilateral pitting oedema (+/++) and/or WHZ <-2 in the control arm
3. Passes appetite test (consumption of 30g of RUTF within 20 minutes)
4. No medical complications

Previous participant inclusion criteria:
1. Children aged 6 to 59 months
2. Diagnosed with uncomplicated acute malnutrition and eligible for CMAM treatment, defined as <125mm MUAC and/or bilateral pitting oedema (+) in the intervention arm or <125mm MUAC

and/or bilateral pitting oedema (++/+++) and/or WHZ <-2 in the control arm
3. Passes appetite test (consumption of 30g of RUTF within 20 minutes)
4. No medical complications

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
2400 acutely malnourished children, with 600 in each arm in each country

Total final enrolment
4110

Participant exclusion criteria
Current participant exclusion criteria as of 01/04/2019:
1. ≥125 mm MUAC
2. Failed appetite test (requires inpatient treatment)
3. Medical complications requiring inpatient treatment, as per international guidelines/ IMCI danger signs including but not limited to:
3.1. Oedema (+++ or higher)
3.2. Anorexia, no appetite
3.3. Intractable vomiting
3.4. Convulsions
3.5. Lethargy, not alert
3.6. Unconsciousness
3.7. Hypoglycaemia
3.8. High fever
3.9. Hypothermia
3.10. Severe dehydration
3.11. Lower respiratory tract infection
3.12. Severe anaemia
3.13. Skin lesions

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3.10. Severe dehydration
3.11. Lower respiratory tract infection
3.12. Severe anaemia
3.13. Skin lesions

Recruitment start date
08/05/2017

Recruitment end date
31/03/2018

Locations

Countries of recruitment
Kenya

South Sudan

Study participating centre
International Rescue Committee, Kenya
Galana Road
PO Box 62727
Kilimani
Kenya
-

Study participating centre
ACF – International, South Sudan Mission
Plot 28, Block AXT, 2nd class,
Hai Cinema
Juba Town
South Sudan
-

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT

Sponsor type
University/education

Website
www.lshtm.ac.uk

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation

Alternative Name(s)
CIFF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
United States Agency for International Development/Office of Disaster Assistance

Results and Publications

Publication and dissemination plan
The results of this trial will be published in peer reviewed scientific journals and presented at international conferences and at national level from 2018 onwards.

Intention to publish date
30/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Jeanette Bailey (jeanette.bailey @rescue.org).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	economic evaluation protocol	24/04/2018		Yes	No
Protocol article	protocol	24/04/2018		Yes	No
Results article	results	09/07/2020	10/07/2020	Yes	No
Other publications		03/02/2021	26/04/2023	Yes	No