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Does treatment for severe malnutrition make children who are short for their age overweight?

Submission date
19/04/2018

Recruitment status
No longer recruiting

Registration date
15/05/2018

Overall study status
Completed

Last Edited
19/12/2018

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
A child that becomes severely thin due to malnutrition requires specialised treatment with medicines and a ready-to eat food (RUTF) that contains all of the necessary ingredients for recovery. Children can be identified for treatment using a tape that measures the circumference at the middle of the upper part of the arm. A potential problem is that if a child is very small for their age, the measurement of the arm might indicate that the child needs treatment when in fact the child has a small circumference because they are small for their age and may not be malnourished. The ready to eat food contains a lot of oil and it is a concern that giving this specialised food to small children who may not be malnourished might cause them to become overweight or develop too much fat as a result of treatment. Obesity is a risk factor for diseases in later life. The aim of this study is to identify whether giving treatment to children who have been identified using the measurement of the arm and are short for their age causes them to become overweight or have more fat than normal following treatment.

Who can participate?
The study recruited all children between the ages of 6 to 59 months who were identified as having severe malnutrition using measurement of the upper arm circumference and were admitted to a treatment programme for malnutrition.

What does the study involve?
The treatment given to the study participants was identical to the treatment given to any severely malnourished child being treated in Ministry of Health clinics in Malawi. The children were discharged as cured according to national guidelines for treatment. For study participants, additional measurements were made of the thickness of a fold of fat on the upper arm (the Triceps Skin Fold).

What are the possible benefits and risks of participating?
The treatment followed standard government guidelines and was no different to the treatment offered to children not enrolled in the study. No incentives were given for participation and there was no additional risk attached to participation in the study.

Where is the study run from?
The study participants were recruited from a total of five Ministry of Health clinics in Lilongwe District in Malawi: Nsaru, Nthondo, Nathenje, Chiwamba and Chilobwe.

When is the study starting and how long is it expected to run for?
The study enrolled children from March 2011 to March 2012.

Who is funding the study?
Family Health International (FHI 360) Food and Nutritional Technical Assistance. The cost of the Harpeneden Calipers was met by Valid International Ltd.

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
4001-08-1-01/4001-VALID- 00/Task Order 4.

Study information

Scientific Title
Does treatment for severe acute malnutrition for children aged 6-59 months, identified by Mid-Upper Arm Circumference and that are less than 65 cm or have low height for age and treated with Ready to Use Therapeutic Food cause the child to become overweight or obese following cure?

Study objectives
Height cut-offs are frequently used as a proxy for an age of 6 months to identify infants not eligible for treatment with ready-to-use therapeutic foods (RUTF) although this may exclude stunted children aged 6 months or older. This study examined whether stunted children aged 6 months or older with severe acute malnutrition (SAM), identified by mid-upper arm circumference (MUAC), and treated with RUTF were overweight or had excess adiposity following cure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Sciences Research Committee of Malawi, 30/11/2010, Protocol #817 MED/4/36c

Study design
Single-centre observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Overweight following treatment for severe acute malnutrition

Interventions
Children aged 6 to 59 months were enrolled in outpatient treatment for SAM if they had a MUAC less than 115 mm without medical complications irrespective of height on admission. 163 children were discharged as cured when a MUAC of 125 mm or greater was obtained for 2 consecutive clinic visits and the child was clinically well. MUAC, triceps skin fold (TSF) thickness and weight were measured at each visit and height was measured on admission and discharge.

Intervention Type
Other

Primary outcome measure
Weight for height z-score on discharge

Secondary outcome measures

1. Triceps skin fold for age z-score on discharge
2. Arm fat index for age z-score on discharge
3. Weight for age z score on discharge

Overall study start date
16/12/2008

Completion date
18/12/2013

Eligibility

Key inclusion criteria
1. Aged 6 - 59 months
2. Mid upper arm circumference <11.5cm
3. Good appetite for ready-to-use therapeutic food
4. No medical complications requiring transfer to hospital
5. Consent from carer to participate

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
N/A

Key exclusion criteria
1. Aged <6 months or >59 months
2. MUAC >11.5cm
3. Anorexia
4. Any medical complication requiring transfer to hospital
5. Refusal of consent

Date of first enrolment
01/03/2011

Date of final enrolment
29/03/2012

Locations

Countries of recruitment
Malawi

Study participating centre
Lilongwe Ditrict
Malawi
N/A

Sponsor information

Organisation
Valid International

Sponsor details
35 Leopold Street
Oxford
United Kingdom
OX4 1TW

Sponsor type
Research organisation

ROR
https://ror.org/00sb6vz77

Funder(s)

Funder type
Not defined

Funder Name
FHI 360

Alternative Name(s)
Family Health International

Funding Body Type
Private sector organisation

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

Location
United States of America

Funder Name
Valid International

Results and Publications

Publication and dissemination plan
Submitted for peer review April 2018

Intention to publish date
31/05/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://figshare.com/articles/MUAC_discharge_from_OTP_and_excess_adiposity/6200759). The study data is provided in Comma Separated Values (CSV) format. It is available now and will be available permanently to any user for any type of analysis. Participation in the study was by informed consent.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/12/2018		Yes	No