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Management of Acute Malnutrition in Infants aged <6 months: Improving the evidence underlying new WHO Malnutrition Guidelines

Submission date
11/10/2017

Recruitment status
No longer recruiting

Registration date
09/11/2017

Overall study status
Completed

Last Edited
30/11/2022

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
Acute malnutrition is a major global public health problem causing over one million child deaths each year. Malnutrition is a serious condition that occurs when someone does not get the right amount of nutrients, leading to weight loss and other helath issues. Over the last decade, treatment of acute malnutrition in children aged 6-59 month has been revolutionized by a public health-orientated model of care, "Community-based Management of Acute Malnutrition" (CMAM). In contrast, acute malnutrition among infants aged under 6 months (infants<6m) remains relatively neglected. This has been partially addressed in the recently released 2013 World Health Organization Guideline on the Management of Severe Acute Malnutrition in Infants and Children. These guidelines however are based on low quality evidence. There is a need to improve the evidence base with data on assessment tools/criteria for infants less than 6 months old with acute malnutrition and effectiveness of the new guidelines, in their current form, for treating infants less than 6 months with acute malnutrition. The aim of this study is to provide critical background/baseline data towards future intervention trials exploring improved effectiveness of treating infants less than 6 months with acute malnutrition.

Who can participate?
Part 1: Infants less than six months old. Part 2: Infants aged 4-8 weeks who are either severely or not severely malnourished.

What does the study involve?
This study contains two parts. The first part is a survey of all infants aged six months and under conducted post-harvest and pre harvest season to measure the amount of infants suffering from malnutrition. The second part of the study is a follow up study. Participants will be chosen as those who were either not suffering from acute malnutrition and those who were severely malnourished. Participants are enrolled when they are 4-8 weeks old and followed up until they become six months or for 180 days. They are surveyed to see how malnourished they are and are measured for their weight, length and body measurements.

What are the possible benefits and risks of participating?
There may be advantages by taking part in research activities. The advantage of getting involved in this study is that it may be possible to determine the causes of children's malnutrition (if present) and to guide the mother/caregiver appropriately as to where to seek treatment for malnutrition. Sometimes some studies may cause harm to the subject or make feeling of discomfort. The risk of this study is that, the mother may feel uncomfortable to answer some portion of the Self Reported Questionnaire (SRQ20) and Quality of Life (QOL) questionnaire. While measuring the length, mid-upper-arm-circumference and body weight of the child, s/he may feel uncomfortable, but these are not harmful for the child. The same procedures for measuring the child are common and have been used in previous research studies.

Where is the study run from?
This study is being run by Save the Children (USA) and takes place in Bangladesh.

When is the study starting and how long is it expected to run for?
September 2014-November 2015

Who is funding the study?
Margaret A. Cargill Foundation (USA)

Who is the main contact?
Dr M Munirul Islam
Ms Nichola Connell

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PR-14112

Study information

Scientific Title
Severe malnutrition in infants aged <6months – seasonal prevalence, outcomes and risk factors in Bangladesh: Repeat cross sectional surveys and a prospective cohort study

Study objectives
This is a prevalence survey to estimate the prevalence rate of infants<6 months old suffering from acute malnutrition. It includes a prospective follow-up component: To estimate the proportions of infants in Group A still being as ‘severely acute malnourished’ and proportion of children in Group B has become ‘severely acute malnourished’ at the end of 6 mo of age (180 completed days).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), 01/03/2015

Study design
Observational cross sectional survey and prospective follow-up cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Malnurishment

Interventions
This study had two components. The first component is an observational study (an initial cross sectional survey among 742 infants<6m) conducted in Barisal Sadar upzila during the post-harvest season and again the survey is repeated during the pre-harvest season. All infants <6 mo are eligible until the desired number of infants is surveyed.

The second component is a prospective follow-up of at least 62 infants with severe acute malnutrition (WLZ <-3 and or with bipedal pitting oedema) as 'severely malnourished infant' (Group A) and at least 62 infants who are not suffering from acute malnutrition (weight-for-length ≥-2 to <2 z-scores and absence of any grade of oedema) as 'not severely malnourished infant' (Group B). An added indicator would be mid upper arm circumference (MUAC), if this is found to be suitable and appropriate for defining malnutrition like the older children after the prevalence survey is over. These both group of infants were enrolled when they were 4-6 weeks old and were followed up until they became 6 months or completed 180 days old. All infants in Group A were referred to a facility which was equipped to treat the young infants suffering from severe acute malnutrition.

Intervention Type
Not Specified

Primary outcome measure
Prevalence survey:
Prevalence rate of infants<6 months old suffering from acute malnutrition was measured by number of infants suffering from acute malnutrition among the infants considered for the surveys.

Prospective Follow-up component:
Proportion of infants in Group A still being as 'severely acute malnourished' and proportion of children in Group B has become 'severely acute malnourished' at the end of 6 mo of age (180 completed days).

Secondary outcome measures
Prevalence survey:
Secondary outcome variables were current feeding practices, mostly focusing on 24 hour recall.

Prospective cohort study:
1. Mortality is measured as the proportion of initially well control infants who developed SAM at 6 months age;
2. Weight for length is measured as the changes in and absolute values of weight-for-length z-score (WLZ), weight-for-age z-score (WAZ), and length-for-age z-score (LAZ).

Overall study start date
01/09/2014

Completion date
18/11/2015

Eligibility

Key inclusion criteria
Prevalence survey:
Infants<6 months old.

Prospective cohort study:
Group A:
4-8 weeks old of either sex as ‘severe acute malnourished infant’ who have defined by weight-for-length <-3 z-score and or with presence of bilateral pitting oedema.

Group B:
4-8 weeks old of either sex as not severely acute malnourished infant’ who have weight-for-length ≥-2 to <2 z-scores and absence of bilateral pitting oedema.

Participant type(s)
Mixed

Age group
Child

Upper age limit
6 Months

Sex
Both

Target number of participants
Prevalence survey: 742 (post-harvest survey) and another 742 (pre-harvest survey); Prospective cohort study: 77 in each group.

Key exclusion criteria
Prevalence survey:
>6 months old infants.

Prospective Follow-up Study:
Other than the mentioned inclusion criteria

Date of first enrolment
29/03/2015

Date of final enrolment
19/10/2015

Locations

Countries of recruitment
Bangladesh

England

Kenya

United Kingdom

United States of America

Study participating centre
International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)
Dhaka
Bangladesh
1212

Study participating centre
Save the Children Bangladesh
Dhaka
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Study participating centre
Save the Children USA
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Study participating centre
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Study participating centre
London School of Hygiene & Tropical Medicine
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Study participating centre
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Sponsor information

Organisation
Department of Global Health, Save the Children USA

Sponsor details
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20002

Sponsor type
Other

ROR
https://ror.org/036jr6x18

Funder(s)

Funder type
Charity

Funder Name
Margaret A. Cargill Foundation, USA.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Study protocol will be available upon request along with data analysis plan.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2019		Yes	No
Other publications	Qualitative results	03/05/2018	30/11/2022	Yes	No