

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

☐ Prospectively registered

☐ Protocol

Registration date

09/11/2017

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

30/11/2022

Condition category

Nutritional, Metabolic, Endocrine

☐ 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 health issues. Over the last decade, treatment of acute malnutrition in children aged 6-59 months 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

Contact name

Dr M Munirul Islam

Contact details

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Protocol serial number

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

Primary study design

Observational

Study design

Observational cross sectional survey and prospective follow-up cohort study

Study type(s)

Other

Health condition(s) or problem(s) studied

Malnourishment

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(s)

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).

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

6 Months

Sex

All

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

United Kingdom

England

Bangladesh

Kenya

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

Bangladesh

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Study participating centre

Save the Children USA

Washington DC

United States of America

20002

Study participating centre

Emergency Nutrition Network

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Study participating centre

London School of Hygiene & Tropical Medicine

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Study participating centre

KEMRI/Wellcome Trust Research Programme

Kenya

43640-00100

Sponsor information**Organisation**

Department of Global Health, Save the Children USA

ROR

<https://ror.org/036jr6x18>

Funder(s)

Funder type

Charity

Funder Name

Margaret A. Cargill Foundation, USA.

Results and Publications

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