Community-based management of severe acute malnutrition in India: New evidence from Bihar

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/12/2014		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
29/01/2015	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
08/04/2015	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Background and study aims

According to the third Indian National Family Health Survey-3 (NFHS-3) conducted in 2005-06, 19.8% of children <5 years of age were wasted, while 6.4% suffered from severe acute malnutrition (SAM) in India. While the principal strategy remains inpatient care through Nutritional Rehabilitation Centers and Malnutrition Treatment Centers, there is a growing consensus within India that adoption of Community-Based Management of Acute Malnutrition (CMAM) is crucial to achieving widespread, effective coverage and treatment of all children with SAM.

Following widespread flooding in Bihar, Médecins Sans Frontières (MSF) conducted a household based survey in Darbhanga which found the prevalence of wasting and SAM in children younger than 5 years was 19.4% and 4.8%, respectively. Consequently, under a memorandum of understanding with the district authorities and thereafter with consent from the Bihar State Health Society, in February 2009 MSF initiated a CMAM program in Biraul block, Darbhanga district.

The CMAM model has been extensively used outside India, with over 50 countries adopting this approach as their first-line strategy for treating SAM. CMAM is based on principles that acknowledge both the need for prolonged treatment and the small proportion of children with SAM who require inpatient care for medical reasons, and on evidence that ambulatory management in the community can be a cost-effective solution from both societal and healthcare provider perspectives. A standard CMAM program consists of treatment sites close to the community where the children with 'uncomplicated' SAM, who constitute the majority of patients, can be seen weekly, and an inpatient facility ('Stabilization Center') that admits only children with SAM plus associated medical complications requiring specialist medical attention, and keeping them only until they recover enough to continue treatment as outpatients in the community.

In this study we look at the routine programme data that has been collected over the life of the programme and present it as an evaluation of the programme as a whole, to see how effective it has been compared to international and national standards. We also present the challenges that the programme faced and possible solutions for policy makers to consider in future decision making.

Who can participate?
Observational study – not applicable

What does the study involve? Observational study – not applicable

What are the possible benefits and risks of participating? Observational study – not applicable

Where is the study run from? Biraul Block, District Dharbhnaga, Bihar, India

When is the study starting and how long is it expected to run for? Observational study – not applicable Analysis of data collected from February 2009 to November 2011. Analyse done between January 2014 and March 2014.

Who is funding the study? Médecins Sans Frontières

Who is the main contact? Dr Temmy Sunyoto

Contact information

Type(s)

Public

Contact name

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Community-based management of severe acute malnutrition in India: New evidence from Bihar: an observational study

Study objectives

This study is an observational study describing the characteristics and outcomes of 8,274 children with severe acute malnutrition treated by MSF in Dharbhangha district, Bihar, India between February 2009—September 2011 in a routine Community Management of Acute Malnutrition (CMAM) programme. The routinely collected programme data has been retrospectively analysed in this study to provide local policy makers with additional evidence of models of care for severely acute malnutrition in 6 month to 5 year old children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This analysis met the Médecins Sans Frontières Institutional Ethics Review Committee criteria for a study involving routinely collected program data. The program utilized a widely recognised treatment model (CMAM) for SAM and was conducted under a memorandum of understanding with the district authorities and thereafter with consent of the Bihar State Health Society, the usual procedure for NGOs operating in this context. All electronic data were analyzed anonymously.

Study design

Single center observational retrospective cohort study using routinely collected programme data.

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

The condition being studied is Severe Acute Malnitrition (SAM) in children between the ages of 6-59 months.

Interventions

We retrospectively analysed the routinely collected programme data from the CMAM programme, looking at exit outcomes, programme indicators and other challenges facing the implementation of CMAM in this context.

Intervention Type

Other

Primary outcome measure

We examined anthropometric and socio-demographic admission and exit characteristics, and classified analysis by discharge as cure, default, death or non-responder.

Secondary outcome measures

We examined risk factors for children defaulting from the programme by analysing anthropometric and socio-demographic criteria at the point of entry to the programme to see if there was any association with risk of defaulting from the programme.

Overall study start date

01/01/2004

Completion date

01/03/2014

Eligibility

Key inclusion criteria

All children with severe acute malnutrition presenting and admitted to the CMAM programme between February 2009 and September 2011.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Not applicable

Key exclusion criteria

No exclusion criteria.

Date of first enrolment 01/01/2014

Date of final enrolment 01/03/2014

Locations

Countries of recruitment India

Study participating centre Biraul Block, District Dharbhnaga, Bihar India

Sponsor information

Organisation

Médecins Sans Frontières

Sponsor details

C203, Defence Colony New Delhi India 110024

Sponsor type

Charity

ROR

https://ror.org/032mwd808

Funder(s)

Funder type

Charity

Funder Name

Médecins Sans Frontières

Results and Publications

Publication and dissemination plan

Planning to publish in the American Journal of Clinical Nutrition, April 2015. Dissemination will be in India to stakeholders and policy makers in India involved with nutrition.

Intention to publish date 30/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2015		Yes	No