

Optimizing the use of antibiotics in uncomplicated severe acute malnutrition management at the community level

Submission date 27/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/01/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/01/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Children with straightforward severe acute malnutrition (SAM) shouldn't need to stay in the hospital; instead, they can be treated as outpatients and given a course of oral antibiotics like amoxicillin. It's important to note that diarrhea is a common side effect of antibiotic treatment, occurring in about 5-30% of patients.

Considering the widespread use of antibiotics, there are growing concerns about their impact on human health, especially the rise of drug-resistant bacteria. Therefore, it's crucial to optimize the use of antibiotics.

The aim of this study is to assess the clinical outcomes of managing uncomplicated severe acute malnutrition (SAM) at the community level with antibiotics compared to without antibiotics.

Who can participate?

Children aged 6 to 59 months with SAM

What does the study involve?

Participants will be randomly allocated to two groups. Group I will consist of uncomplicated severe acute malnutrition (SAM) children who will receive antibiotics for a week as part of the intervention. Group II will serve as the placebo group, comprising uncomplicated SAM children who will not receive antibiotics but will be given a placebo instead. Both Group I and Group II will undergo a thorough assessment, including a detailed clinical history and physical examination. Additionally, their nutritional status will be assessed through anthropometric measurements.

What are the possible benefits and risks of participating?

This study supports the WHO policy of antibiotic stewardship for rational antibiotic use by reducing the unnecessary use of antibiotics. There are no expected risks.

Where is the study run from?

Indian Council of Medical Research (India)

When is the study starting and how long is it expected to run for?
September 2021 to September 2024

Who is funding the study?
Indian Council of Medical Research (India)

Who is the main contact?
Dr Yashwant Kumar Rao, ykraoneo@yahoo.co.in

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Yashwant Kumar Rao

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

5/9/1338/2020-Nut

Study information

Scientific Title

A randomised controlled trial to study the clinical outcome in the management of uncomplicated severe acute malnutrition children (6 months to 59 months) at the community level with antibiotics against without antibiotics.

Study objectives

Keeping in view the WHO Antimicrobial Stewardship Programmes (ASPs), we need to reassess the use of antibiotics in the management of uncomplicated severe acute malnutrition (SAM) at the community level. Even WHO and GoI have recommended the use of amoxicillin in uncomplicated SAM at the community level and also for community-acquired pneumonia

amoxicillin is recommended. Since amoxicillin is the first-line drug for uncomplicated SAM, community-acquired pneumonia and other respiratory tract infections, its irrational use will increase morbidity and mortality if its resistance occurs. There is a very low proportion of infections in uncomplicated SAM, so there will be added cost and complexity with possible excessive toxicity after the use of amoxicillin. Therefore, we conducted this study to compare the clinical outcome in children with uncomplicated SAM managed with and without antibiotics.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 04/09/2021, Ethics Committee (For Biomedical Health & Research) (Room No. 125, 1st Floor, GSVM Medical College, Kanpur, 208002, India; +91 9919080807; ykraoneo@yahoo.co.in), ref: EC/70/ Apr. / 2020

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Childcare/pre-school, Community, Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Severe acute malnutrition

Interventions

A balanced block randomisation technique was used with a block size of 4 using tables taken from the website <https://www.sealedenvelope.com>.

Group I will be the interventional group of uncomplicated SAM children receiving antibiotics for 1 week (amoxicillin syrup 40-45 mg/kg/day). Group II will be the placebo group of uncomplicated SAM children receiving no antibiotics but only placebo. Both group I and group II will be evaluated with a detailed clinical history physical examination. Their nutritional status will be determined by anthropometric measurement. The medical officer in charge of the local Primary Health Centre (PHC) and Accredited Social Health Activists (ASHA)/Anganwadi Workers (AWW)/Auxiliary Nurse Midwives (ANMs) will be informed about the details of each SAM child identified during the house-to-house visit for further management and help in follow-ups.

Intervention Type

Drug

Pharmaceutical study type(s)

Dose response, Pharmacoeconomic

Phase

Phase III

Drug/device/biological/vaccine name(s)

Oral amoxicillin syrup

Primary outcome measure

1. Clinical outcomes of management of uncomplicated severe acute malnutrition (SAM) at the community level measured using:
 - 1.1. Weight for height z score, weight for age z score, and height for age z score at baseline, 15 days, 30 days, 45 days, 60 days
 - 1.2. Biochemical investigations at baseline and 60 days

Secondary outcome measures

Determinants of risk factors of SAM measured using questionnaire at baseline

Overall study start date

04/09/2021

Completion date

03/09/2024

Eligibility

Key inclusion criteria

Children aged 6 to 59 months with:

1. Weight for height below – 3 standard deviation (SD or Z scores)
2. Malnutrition with bilateral pedal edema or visible severe wasting
3. Mid upper arm circumference (MUAC) <115 mm

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

59 Months

Sex

Both

Target number of participants

362

Key exclusion criteria

1. Any congenital malformation
2. Chronic diseases except HIV and TB
3. Any previous antibiotic use within 14 days
4. SAM with complications

Date of first enrolment

15/11/2021

Date of final enrolment

28/02/2024

Locations**Countries of recruitment**

India

Study participating centre

GSVM Medical College, Kanpur

Swaroop Nagar Kanpur

Uttar Pradesh

Kanpur Nagar

India

208002

Sponsor information**Organisation**

Indian Council of Medical Research

Sponsor details

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Sponsor type

Government

Website

<http://www.icmr.nic.in/>

ROR

<https://ror.org/0492wrx28>

Funder(s)

Funder type

Government

Funder Name

Indian Council of Medical Research

Alternative Name(s)

Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, . . . , ICMR, ICMRDELHI, ...

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

India

Results and Publications

Publication and dissemination plan

Published in Indian Journal of Pediatrics

Future Plan: WHO Bulletin

Intention to publish date

01/03/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request: Dr Yashwant Kumar Rao (ykraoneo@yahoo.co.in).

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

01/06/2023

28/12/2023

Yes

No