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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

Registration date
12/01/2024

Overall study status
Completed

Last Edited
12/01/2024

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
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

Contact details
P4, GSVM Medical College, Kanpur Nagar
Kanpur Nagar
India
208002
+91 9919080807
ykraoneo@yahoo.co.in

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, lst FIoor, GSVM Medica! 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 (amoxycillin 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
V. Ramalingaswami Bhawan, PO Box No. 4911. Ansari Nagar
New Delhi
India
110029
+91-11-26588895
icmrhqds@sansad.nic.in

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?

Results article	01/06/2023	28/12/2023	Yes	No