



Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM

Scientific Title An adaptive multi-arm trial to improve clinical outcomes among children recovering from complicated severe acute malnutrition (Co-SAM)

Primary Sponsor Details

Sponsors * Queen Mary University of London

Secondary Sponsor Details

Contact for Public Queries

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Affiliation

Countries of Recruitment *

Kenya

Zambia

Zimbabwe

Source of Funds Queen Mary University of London

Health Condition(s) or Problem(s) Studied * Severe acute malnutrition

Medicine Name * Rifampicin, Isoniazid, Azithromycin

Quantity of medicine required * N/A

7.0 PRINCIPAL INCLUSION CRITERIA *

1. Age 6-59 months, of either sex
2. Hospitalised with complicated severe acute malnutrition, as per WHO definition
3. Started transition from therapeutic milk feeds to RUTF
4. Caregiver willing and able to attend the study clinic for all visits
5. Caregiver able and willing to give informed consent

7.1 PRINCIPAL EXCLUSION CRITERIA *

Any acute or chronic condition which mean that receipt of one or more study interventions, or participation in the trial, would not be advisable

7.2 PRIMARY END POINTS *

The primary endpoints for this trial will be death or first hospitalisation or failed nutritional recovery within 24 weeks post-randomisation.

9.0 DESIGN OF THE TRIAL

Type of trial * Opened

If controlled

Randomised

Single Blind

Double Blind

Parallel group

Cross over

Other

If yes to other, specify

If controlled, specify the comparator

Other medicinal product(s) No

Placebo No

Other No

If yes to other, specify

Other

Expected Number of participants in Zimbabwe *	422
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	422
Total participants worldwide *	1266

Time period for the trial * 1 Jan 2024 to 31 Dec 2026