Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	CT176, Therapeutic Approaches to Malnutrition Enteropathy (TAME)
Scientific Title	Therapeutic Approaches to Malnutrition Enteropathy: Phase II Trials of Four Novel Interventions in Children in Zambia and Zimbabwe

Primary Sponsor Details

Sponsors *	Queen Mary University of London Sponsorship

Secondary Sponsor Details

Contact for Public Queries

Name *	Dr Mutsawashe Filda Bwakura-Dangarembizi
Designation *	Principal Investigator
Email *	abc@abc.com
Phone number *	243-306028
Postal Address*	N/A
Affiliation	

Contact for Scientific Queries

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Postal Address*	N/A
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Countries of Recruitment *

Zambia and Zimbabwe

Source of Funds	QUEEN MARY UNIVERSITY OF LONDON SPONSORSHIP
Health Condition(s) or Problem(s) Studied *	Malnutrition enteropathy in African children with severe acute malnutrition
Medicine Name *	Teduglutide, Budesonide, Bovine Colostrum, N-acetylglucosamine
Quantity of medicine required *	n/a

7.0 PRINCIPAL INCLUSION CRITERIA *

1. Age 6-59 months
2. Inpatient in the paediatric wards of one of the research sites
3. Severe Acute Malnutrition (Weight-for-length z score of less than -3 or mid arm upper circumference of less than 11.5cm, and/or bilateral pedal oedema)
4. Completed resuscitation phase of nutritional rehabilitation; and clinically stable*
5. Written, informed consent from the primary caregiver
6. Caregiver is willing to remain in hospital for the duration of the study treatment (14 days).

*Judged by the medical team on any case-by-case basis, but in general a child without shock, hypothermia, hypoglycaemia or reduced consious level.

7.1 PRINCIPAL EXCLUSION CRITERIA *

1. Clinically unstable*
2. Less than 5kg body weight;
3. Neurological disability which would explain or partly explain poor feeding;
4. Oro-facial abnormalities which would explain or partly explain poor feeding;
5. Caregiver unwilling to consent to child HIV testing
6. Haemoglobin concentration < 6g/dl at the time of enrollment;
7. Caregiver unwilling to remain in hospital for the duration of the study treatment;
8. Any underlying condition, other than HIV, which in the opinion of the investigator would put the subject at undue risk of failing study completion or would interfere with analysis of study results;
9. Contraindication to any of the trial treatments (e.g allergy to cow's milk protein.

*As assesed by the medical team on a case-by-case basis, but in general a clinically unstable child would include shock, hypothermia, hypoglycaemia or reduced consious level.

7.2 PRIMARY END POINTS *

The primary endpoints for this trial will be measured on day 14 (allowable window 14 to 18 days) after initiating treatment by analysis of faecal biomarkers. Gut inflammation will be measured as a composite score of faecal myeloperoxidase, neopterin and alpha-1 antitrypsin, as outlined in section 13.

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)	
Placebo	
Other	
If yes to other, specify	
Other	

Expected Number of participants in Zimbabwe *	120

Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	225 children in total will be enrolled across Zimbabwe and Zambia (up to 120 in Zimbabwe). Allowing for 20% death/loss to follow-up (see below) we will have 180 evaluable children
Total participants worldwide *	225

Time period for the trial * 2019-2022