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Comparison of 10% milk ready-to-use food to 25% milk ready-to-use food in the treatment of severely malnourished, Malawian children

Submission date	Recruitment status
01/06/2009	No longer recruiting
Registration date	**Overall study status**
04/06/2009	Completed
Last Edited	**Condition category**
29/12/2020	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

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
Randomised, double-blind controlled clinical effectiveness trial comparing 10% milk ready-to-use food with 25% milk ready-to-use food (RUTF) in the treatment of severe acute malnutrition in rural Malawian children

Study objectives
The proposed study tests the hypothesis that 12 - 60 month-old children with severe acute malnutrition whose caretakers are provided with supplements and counselling to feed the child with 175 kcal/kg/d of either 10% milk ready-to-use therapeutic food (RUTF) or 25% milk RUTF are likely to recover at a similar rate during an 8-week intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Washington University Human Research Protection Office approved on the 21st May 2008 (ref: FWA00002284; 08-0513)

Study design
Randomised double-blind controlled clinical effectiveness trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Childhood severe acute malnutrition

Interventions
The randomised food product, 10% milk RUTF or 25% milk RUTF, sufficient for two weeks' feeding to the treated child will be given to the subject's caretaker with instructions on daily feeding methods and advice not to share the food product with other members of the household. Children and their caretakers will return for follow-up, food collection, and measurements and monitoring of the child's growth and any adverse events every 2 weeks.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ready-to-use therapeutic food (RUTF)

Primary outcome measure
Recovery, defined as weight-for-height z-score greater than -2 on two consecutive visits.

Secondary outcome measures
1. Rates of gain in weight, height and mid-upper arm circumference
2. Adverse outcomes such as death
3. Number of days of fever, cough and diarrhoea

Measured at each return visit, i.e. every two weeks until the child reached the final outcome of recovery/death/another outcome.

Overall study start date
06/01/2008

Completion date
05/01/2009

Eligibility

Key inclusion criteria
1. Children aged 12 - 60 months, either sex
2. Suffering from severe acute malnutrition
3. Reside within 7 kilometres of and present to one of the 15 feeding sites during the recruitment period

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Months

Upper age limit
60 Months

Sex
Both

Target number of participants
1800

Total final enrolment
1874

Key exclusion criteria
1. Not permanent residents in the vicinity of one of the feeding sites
2. Severe chronic illness, e.g., cerebral palsy
3. A history of peanut allergy or anaphylaxis resulting from any food
4. Receiving other supplementary food
5. Participating in another research study

Date of first enrolment
06/01/2008

Date of final enrolment
05/01/2009

Locations

Countries of recruitment
Malawi

United States of America

Study participating centre
Washington University School of Medicine
St. Louis
United States of America
63110

Sponsor information

Organisation
University of Malawi College of Medicine (Malawi)

Sponsor details
Private Bag 360
Blantyre
Malawi
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Sponsor type
University/education

Website
http://www.medcol.mw/

ROR
https://ror.org/04vtx5s55

Funder(s)

Funder type
Charity

Funder Name
Hickey Family Foundation (USA) - Academy for Educational Development

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010	29/12/2020	Yes	No