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A comparison of diets to treat moderate childhood malnutrition

Submission date	Recruitment status	[ ] Prospectively registered
01/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/05/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/05/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
2620-22-0-00-P-0089

Study information

Scientific Title
Randomised controlled trial comparing the impacts of feeding with milk/peanut ready-to-use therapeutic food (RUTF), soy/peanut RUTF, and corn-soy blend (CSB) among children with moderate acute malnutrition in Malawi

Study objectives
12 - 60 month-old children with moderate acute malnutrition (weight-for-height z score [WHZ] greater than -3 and less than -2) whose caretakers are provided with supplements and counseling to feed the child with 75 kcal/kg/day of either milk/peanut ready-to-use therapeutic food (MP-RUTF) or soy/peanut ready-to-use therapeutic food (SP-RUTF) are more likely to recover from moderate acute malnutrition during an eight-week intervention than comparable children receiving isoenergetic rations of corn-soy blend (CSB); in addition among children receiving MP-RUTF or SP-RUTF, the recovery rate will not differ by more than 10%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. College of Medicine Research and Ethics Committee (Malawi) on the 17th July 2007 (ref: P.06 /07/564)
2. Washington University Human Studies Committee on the 18th July 2007 (ref: 07-0642)

Study design
Randomised, investigator blinded clinical effectiveness trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Moderate malnutrition

Interventions
Feeding with one of three foods:
1. Ready-to-use milk/peanut fortified spread
2. Ready-to-use soy/peanut fortified spread
3. Corn soy blend

Children will receive isoenergetic amounts of one of the above three foods for up to eight weeks. The amount of food given is sufficient to provide 75 kcal/kg/d. The children will be followed biweekly, having weight, length, and mid-upper arm circumference measured; and the number of days of fever, cough and diarrhoea recorded from caretaker's report. Follow-up is for eight weeks.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nutritional supplements

Primary outcome measure
Recovery, measured at the completion of the feeding period, usually eight weeks.

Secondary outcome measures
1. Weight gain, measured after four weeks
2. Height gain, measured after four weeks
3. Mid-upper arm circumference gain, measured after four weeks

Overall study start date
01/08/2007

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Children aged 12 - 60 months
2. Moderate acute malnutrition using the World Health Organization (WHO) criteria (WHZ greater than -3 and less than -2)
3. Reside within 7 km
4. Present to one of seven supplementary feeding sites in southern Malawi during the study 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
1400

Key exclusion criteria
1. Children who are not permanent residents in the vicinity of the local health centre (distance from home to health centre greater than 7 km)
2. Have severe chronic illnesses such as cerebral palsy
3. Have a history of peanut allergy or anaphylaxis resulting from any food
4. Receive other supplementary food from a government or charitable agency
5. Participating in another research study

Date of first enrolment
01/08/2007

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Malawi

United States of America

Study participating centre
Department of Pediatrics
St. Louis, MO
United States of America
63110

Sponsor information

Organisation
Academy for Educational Development (AED) (USA)

Sponsor details
1825 Connecticut Ave NW
Washington, DC
United States of America
20009-5721

Sponsor type

Research organisation

Website
http://www.aed.org/index.cfm

ROR
https://ror.org/034s15752

Funder(s)

Funder type
Research organisation

Funder Name
Academy for Educational Development (AED) (USA)

Funder Name
Allen Foundation Inc. (USA)

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