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Equivalency trial of a locally produced alternative ready-to-use therapeutic food (RUTF) in Ghana

Submission date
22/11/2017

Recruitment status
No longer recruiting

Registration date
01/12/2017

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Ready-to-Use Therapeutic Foods (RUTF) are high-energy, lipid-based spreads that can be used for the treatment of malnutrition. To provide government and international agencies with an alternative to the standard treatment, this study aims to compare an alternative ready-to-use therapeutic food (RUTF) with the standard RUTF.

Who can participate?
Ghanaian children aged 6-59 months with moderate or severe acute malnutrition at rural health clinics throughout the Brong Ahafo region

What does the study involve?
Participating children are randomly allocated to one of two groups. One group receives the standard formula RUTF and the other group receives an alternative formula RUTF with locally sourced ingredients. Enough food for two weeks' feeding is given to the child's caretaker with instructions on daily feeding methods and they are advised not to share the food product with other members of the household. Children and caretakers return for follow-up, food collection, measurements, and monitoring of the child's growth and any side effects every 2 weeks until recovery or failure (death, transfer to hospital for inpatient care, remaining malnourished at 12 weeks). At follow-up, caretakers are questioned about symptoms of acute illness, compliance with study foods and food intolerance or allergy. If needed an additional 2 weeks of therapeutic foods is dispensed. If the child is judged to have altered mental status, respiratory (breathing) distress or an acute clinical illness needing medical care, the child is referred to the health center for complicated malnutrition and withdrawn from the study.

What are the possible benefits and risks of participating?
In this region of Ghana there are no alternatives and no home-based treatments for moderate or severe acute malnutrition. There is no cost to the participants, and the study provides all medicines, tests and medical care related to the treatment of acute malnutrition for free to the participants. The child has enough study food provided at home for the recovery of acute malnutrition and is monitored regularly during recovery. This may result in fewer complications

(diarrhoea, respiratory illnesses) as the child recovers. Medical treatments that are needed are provided during these follow-up visits. Additionally, other malnourished children may benefit because this study aims to learn if both of these foods promote full nutritional recovery from acute malnutrition. If both foods are equivalent this could mean that more children could have access to treatment as the alternative RUTF is lower in cost. There are certain risks and discomforts that may be associated with this study. They are rare but may include rashes, itching or cough as a result of food allergies to the food. If a child develops any of these problems, caregivers are advised to stop feeding him/her the food and return to the health center to have him/her examined by one of the study doctors.

Where is the study run from?
Health Clinics in Brong Ahafo region of Ghana

When is the study starting and how long is it expected to run for?
May 2016 to April 2018

Who is funding the study?
Children's Investment Fund Foundation (UK)

Who is the main contact?
1. Dr Mark Manary
2. Mrs Meghan Callaghan-Gillespie

Contact information

Type(s)
Public

Contact name
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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201604032

Study information

Scientific Title
Comparison of a locally produced, alternative therapeutic food to a standard ready-to-use therapeutic food (RUTF) for the treatment of acute malnutrition in children from the Brong Ahafo region of Ghana

Study objectives
The difference in recovery rates between the locally produced alternative RUTF and standard RUTF will be no greater than 5 percent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Washington University in St. Louis Institutional Review Board, original approval 04/05/2016, continuing review approval 27/04/2017, ref: IRB ID #:201604032
2. Noguchi Memorial Institute for Medical Research Institutional Review Board, original approval 02/03/2016, continuing review approval 04/05/2017, ref: CPN 078/15-16

Study design
Randomised double-blinded controlled clinical equivalency trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Acute malnutrition as defined by weight for height z-score (WHZ) < -2, Mid-Upper Arm Circumference (MUAC) <12.5 cm, or bipedal edema

Interventions
Randomisation consists of random 1:1 permuted blocks of 4 for the entire study rather than at each study site. Within the randomised blocks two colors were randomly assigned to the intervention group and 2 colors to the control group. To allocate children to a food group, caretakers chose a sealed envelope that contained 1 of 4 colors (permuted randomised blocks). The color will be recorded separately from the child's clinical measurements and researchers involved in the randomisation process do not know which color corresponds to which food. The drivers who distribute the food will not assess the participant.

Control: ready-to-use therapeutic food (RUTF) - standard formula
Intervention: ready-to-use therapeutic food (RUTF) - alternative formula with locally sourced ingredients

The randomized therapeutic food sufficient for two weeks' feeding will be given to the enrolled subject's caretaker with instructions on daily feeding methods and advised not to share the food product with other members of the household. Subjects and caretakers will return for follow-up, food collection, measurements, and monitoring of the child's growth and any adverse events every two weeks until recovery (WHZ ≥ -2 and MUAC≥ 12.5 by 12 weeks) or failure (death, transfer to hospital for inpatient care, remaining malnourished at 12 weeks, default). Children with severe acute malnutrition (SAM) will initially be given oral amoxicillin twice daily for a week. For eligible children with no bipedal edema, a MUAC > 11.5 cm and/or WHZ > -3 the child will receive 75 kcal/kg/day of RUTF, for eligible children with bipedal edema or a MUAC < 11.5 or WHZ < -3 the child will receive 190 kcal/kg/day. Once children with SAM achieve MUAC >11.5 cm, the RUTF dose will be reduced.

At follow-up, caretakers of children will be questioned about symptoms of acute illness, compliance with study foods and food intolerance or allergy. If edema persists or MUAC is less than 12.5 cm, an additional two weeks of therapeutic foods will be dispensed. If the child is judged to have altered mental status, respiratory distress or an acute clinical illness needing medical care, the child will be referred to the health center for complicated SAM and withdrawn from the study.

Children will also be evaluated for kwashiorkor by assessing for bilateral pitting edema. No additional food rations will be distributed when subjects reach an outcome: recovery (MUAC ≥ 12.5), death, development of complicated severe acute malnutrition, transfer to hospital for inpatient care, failure to recover from by 12 weeks, or default.

Intervention Type
Supplement

Primary outcome measure
1. Mid-upper arm circumference, measured with a standard insertion tape to the nearest 0.1 cm every two weeks until recovery
2. Weight for length z-score (weight measured using an electronic scale to the nearest 5 g, length measured to the nearest 0.1 cm using a rigid length board), measured every two weeks until recovery

Secondary outcome measures
1. Other anthropometric measures (weight measured using an electronic scale to the nearest 5 g, length measured to the nearest 0.1 cm using a rigid length board), measured every two weeks until recovery
2. Adverse symptoms, such as stomach pain, vomiting, diarrhea, rash or fever, measured every two weeks until recovery

Overall study start date
01/05/2016

Completion date
01/04/2018

Eligibility

Key inclusion criteria
Children aged 6-59 months with WHZ < -2, MUAC <12.5 cm, or bipedal edema

Participant type(s)
Other

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1800

Total final enrolment
1270

Key exclusion criteria
1. Children currently involved in another research trial or feeding program
2. Developmentally delayed
3. Chronic debilitating illness (such as cerebral palsy)
4. History of peanut or milk allergy
5. Serious adverse effects to the study food (such as an allergic reaction)
6. Received therapy for acute malnutrition within one month prior to presentation

Date of first enrolment
07/02/2017

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Ghana

Study participating centre
Health Clinics in Brong Ahafo region of Ghana
Ghana
03520

Sponsor information

Organisation
Washington University School of Medicine

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Sponsor type
University/education

Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation

Alternative Name(s)
CIFF

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
While no documents are currently available via a public forum, the trialists are willing to share the study protocol on request. Planned publication of the study results in a high-impact peer reviewed journal within 6 months to 1 year of the overall trial end date.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
While the trialists have no plans to share individual deidentified participant data at this time in a public forum, they will be sharing the individual participant data that underlie the results reported in their publication for researchers who provide a methodologically sound proposal and are willing to sign a data access agreement. Those inquiring to use participant level data for further investigation can submit proposals via email to Dr Mark Manary.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/04/2019	18/04/2019	No	No
Results article	results	27/06/2019	03/04/2020	Yes	No
Protocol file			17/08/2022	No	No