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Acceptability, effectiveness and cost-effectiveness of soya maize sorghum-based ready-to-use therapeutic food in treating severe acute malnutrition in children under five in Lusaka, Zambia

Submission date	Recruitment status	[ ] Prospectively registered
29/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/07/2008	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
Irish Aid 07/01

Study information

Scientific Title

Study objectives
1. The acceptability of soya maize sorghum ready-to-use therapeutic food (RUTF) among children is equivalent to that of peanut RUTF
2. The effectiveness of soya maize sorghum RUTF is equivalent to peanut RUTF in the treatment of severe acute malnutrition
3. Soya maize sorghum RUTF is less costly and therefore more cost-effective than peanut RUTF in the treatment of severe acute malnutrition

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the University of Zambia, Biomedical Research Ethics Committee on the 6th May 2008 (Assurance no: FWA00000338 IRB00001131 of IORG0000774; ref: 10-04-08).

Study design
Crossover design for acceptability, followed by a cluster randomised non-blind trial for the effectiveness study finished with a cost-effectiveness analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Severe acute malnutrition

Interventions
Total duration of treatment for the acceptability study is five weeks.

Soya, maize and sorghum based RUTF will be compared to the control of peanut based RUTF. All admitted children in both arms will receive standard dose of medication as per Community-based Therapeutic Care protocol in use in Lusaka. In addition children in the intervention arm will be provided soya, maize and sorghum based RUTF tailored to weight (200 KCal/kg/Day) and children in the control arm will receive peanut based RUTF tailored to weight (200 KCal/kg/day). Both groups will receive the food until exit from the programme.

From experience the average length of stay is 8 weeks and the maximum stay in the programme is 17 weeks, i.e. from time of recruitment until exit from the programme (either cured from severe acute malnutrition, or default, or death, or transfer, or non-cured).

Those children who are discharged cured will be followed up at week 4, 6 months and 12 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Soya maize sorghum ready-to-use therapeutic food (RUTF), peanut RUTF

Primary outcome measure
1. Acceptability study: RUTF acceptability, measured at end of five weeks. Data will be analysed to compare the acceptability of the RUTFs compared.
2. Randomised trial: recovery rate. Data for recovery rate will be measured routinely and analysed on monthly basis, however final analysis will be done at the end of the study period.
3. Cost effectiveness evaluation:
3.1. Incremental cost per death prevented, and per recovered child, measured at the end of the study period
3.2. Probability that the intervention is cost effective for different levels of willingness to pay per outcome (e.g. US$150/DALY gained), measured at the end of the study period

Secondary outcome measures
1. Acceptability study:
1.1. Dietary intake, measured daily during the five week period
1.2. Morbidity, measured daily for the whole duration
1.3. Weight gain, measured at entry, at the end of week 2, the beginning of week 4 and the end of week 5. In week three will be a wash out period.
2. Randomised trial:
2.1. Defaulter rate. Data for default rate will be collected and analysed routinely. However final comparison will be made at the end of the study.
2.2. Average weight gain from baseline (or, in oedematous children, from time of loss of oedema) until exit from the programme. Weight gain will be measured for each individual child and an average taken at the end. This will be done for children who successfully complete the treatment.
2.3. Morbidity (diarrhoea, vomiting, fever, cough). Incidence of morbidity will be compared between the two groups on regular basis (weekly) and at the end of the study.
2.4. Hospital referral. The number of children referred and outcome for referral will be measured and compared at the end of the study.

2.5. Mortality. Mortality data will be collected and analysed routinely. However final analysis will be made at the end of the study and comparison between the two arms will be made.
2.6. Length gain. Data on height will be captured at admission, week four, week eight and at discharge.
3. Cost effectiveness evaluation: cost of Community-based Therapeutic Care, including RUTF, measured at the end of study period

Overall study start date
16/06/2008

Completion date
03/08/2009

Eligibility

Key inclusion criteria
1. Both male and female severely acutely malnourished children in the age range of 6 - 59 months
2. Mid-upper arm circumference less than 110 mm or oedema of + or ++
3. Admitted into the Outpatient Therapeutic Programme at the health centre
4. Good appetite
5. No serious medical complication

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
Acceptability study: 50 children; effectiveness study: 1,604 children (total = 1654)

Key exclusion criteria
There are no exclusion criteria to be used as all severely malnourished children with no complications need to be treated at the health centre level until recovery. However, severely malnourished children who do not have an appetite or have severe medical complications or marasmic-kwashiorkor will be first referred to the stabilisation centre (University Teaching Hospital) straight away. These children will be taken into the study once stabilised at the inpatient unit of University Teaching Hospital. They will receive the respective RUTF being used in the health centre then return to follow up treatment.

Date of first enrolment
16/06/2008

Date of final enrolment
03/08/2009

Locations

Countries of recruitment
Zambia

Study participating centre
Valid Nutrition
Lusaka
Zambia
N/A

Sponsor information

Organisation
Irish Aid (Ireland)

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Sponsor type
Charity

Website
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ROR
https://ror.org/03kyawa63

Funder(s)

Funder type

Charity

Funder Name
Valid Nutrition (UK)

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