

# 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

<b>Submission date</b> 29/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/07/2008	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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).

### Primary study design

Interventional

### Study design

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

### Study type(s)

Treatment

### 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(s)

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

## Key secondary outcome(s)

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

## 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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

59 Months

**Sex**

All

**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)

## ROR

<https://ror.org/03kyawa63>

# Funder(s)

## Funder type

Charity

## Funder Name

Valid Nutrition (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration