

A randomised controlled trial to compare the efficacy of three new formulations of Ready-to-Use Therapeutic Food (RUTF) in the treatment of severe acute childhood malnutrition

Submission date 16/12/2005	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 23/01/2006	Overall study status Completed	☐ Protocol
Last Edited 23/07/2009	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Andrew Seal

Contact details

Centre for International Child Health
Institute of Child Health
30 Guildford Street
London
United Kingdom
WC1N 1EH

Additional identifiers

Protocol serial number

05CH03

Study information

Scientific Title

Acronym

PRONUT Study

Study objectives

In a population of severely malnourished children:

1. Low-milk/chickpea-based RUTF (Ready-to-Use Therapeutic Food) is non-inferior (one-sided equivalence hypothesis) to high-milk/peanut-based RUTF.
2. Probiotic/Prebiotic enhanced ('Synbiotic 2000 Forte') RUTF is superior to standard RUTF.

Due to a delay in the food acceptability pilot studies, the trial was simplified to test only the second hypothesis:

Probiotic/Prebiotic enhanced ('synbiotic 2000 Forte') RUTF is superior to standard RUTF.

Ethics approval required

Old ethics approval format

Ethics approval(s)

College of Medicine Research and Ethics Committee, Malawi (COMREC) (reference number: P03/04/236). Final approval, including amendments: 10th November 2005.

Simplification of study to test only second hypothesis approved April 2006.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Severe acute malnutrition

Interventions

The initial plan was that after initial in-patient stabilisation with F75 milk, enrolled children would be randomised to one of four different types of RUTF:

1. (Control) Standard, high-milk/peanut based RUTF
2. Standard RUTF with added synbiotic
3. New formulation low-milk/chickpea-based RUTF
4. New formulation RUTF with added synbiotic

Due to delays in the food acceptability pilot studies, the trial was simplified prior to start, and as of beginning of enrolment in July 2006 is testing only:

1. (Control) Standard, high-milk/peanut based RUTF
2. Standard RUTF with added synbiotic

The simplified study started enrolling patients on 12th July 2006, and is expected to end in April 2007.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Nutritional cure (%)

Key secondary outcome(s)

1. Death rate (%)
2. Rate of weight gain (g/kg/day)
3. Incidence of illness episodes (including diarrhoea)
4. Length of stay in programme (days)
5. Default rate (%)

Completion date

27/04/2007

Eligibility**Key inclusion criteria**

All children suffering from severe acute malnutrition (World Health Organisation [WHO] criteria: less than 70% weight/height and/or oedema) admitted to Moyo Malnutrition Ward, Queen Elizabeth Hospital, Blantyre, Malawi

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. Children with severe cerebral palsy or obvious dysmorphic syndrome
2. Children less than six months of age or 4 kg weight

Date of first enrolment

27/01/2006

Date of final enrolment

27/04/2007

Locations

Countries of recruitment

United Kingdom

England

Malawi

Study participating centre

Centre for International Child Health

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Institute of Child Health, University College London (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

At registration, prior to 23/07/09: Valid International (UK)

Funder Name

Corrected on 23/07/09: the project was funded from a core grant from the Department for International Development (DFID) (UK) to Concern Worldwide (Ireland)

Results and Publications

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	11/07/2009		Yes	No