

Effect of nutritional intervention with ready to use therapeutic food (RUTF) on blood lipid profiles of moderate to severely malnourished adults receiving antiretroviral therapy (ART)

Submission date 20/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/03/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/03/2009	Condition category Infections and Infestations	<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

Contact name

Dr Sandra Mutuma

Contact details

Valid International/ Nutrition
Addis Abba Road/ Chaholi Road
Alex Masala Close
Plot 4126
Lusaka
Zambia
P.O. Box 50719

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled study assessing the effect of nutritional intervention with ready to use therapeutic food (RUTF) on blood lipid profiles of moderate to severely malnourished adults receiving antiretroviral therapy (ART) in Lusaka, Zambia

Acronym

LRS (Lipid Research Study)

Study objectives

The use of high fat energy dense ready to use therapeutic food in HIV positive malnourished adults receiving antiretroviral therapy (ART) does not produce deleterious changes in their blood lipid profiles.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Zambia Biomedical Research Ethics Committee, approved on 20/11/2008 (ref: 009-10-08)

Study design

Randomised controlled trial

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

HIV and malnutrition

Interventions

Participants will be randomly allocated to the following two arms:

Intervention group: Participants will receive 2 jars/day of RUTF for 3 months, each jar weighs 250g (for 100g RUTF: energy content = 530 kcal, of which 47-59% are from oil and 10% are protein calories) in addition to prescribed ART regimen, nutritional advice and counselling.

Control group: Participants will receive ART, nutritional advice and counselling only

Total duration of interventions: 3 months

This trial will initially be a single-centre trial but may be extended to be a two-centre trial depending on recruitment rates.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Total cholesterol/high density lipoprotein cholesterol (TC/HDL-C) ratio (TC/HDL-c ratio ≥ 5), assessed at baseline, Month 3, 6, 9 and 12 after enrolment into the study.

Secondary outcome measures

The following will be assessed at baseline, Month 3, 6, 9 and 12 after enrolment into the study:

1. Lipid profile:

- 1.1. Mean change in total cholesterol (TC)
- 1.2. Mean change in high density lipoprotein cholesterol (HDL-c)
- 1.3. Mean change in low density lipoprotein cholesterol (LDL-c)
- 1.4. Mean change in total triglycerides (TG)

2. Body composition:

The endpoints will be the correlation between change in TC and in:

- 2.1. Body fat mass proportion
- 2.2. Fat free mass (FFM) proportion
- 2.3. Fat-free mass index (FFMI) which controls for height

3. Nutritional status:

The endpoints will be the correlation between change in TC and in:

- 3.1. Weight (kg)
- 3.2. MUAC (mm)
- 3.3. BMI (kg/m^2)
- 3.4. Waist circumference

Note: Some of the secondary endpoints (e.g., weight, MUAC, waist measurements) may be taken at two weekly intervals from baseline up to Month 3 as well as at the timepoints indicated above.

Overall study start date

26/01/2009

Completion date

30/06/2010

Eligibility

Key inclusion criteria

1. Eligible for ART or has started ART within last 2 weeks
2. Both males and females, age ≥ 18 years to ≤ 49 years
3. mid-upper arm circumference (MUAC) < 22.0 cm
4. Body mass index (BMI) < 17.0 kg/m²
5. CD4 Count > 50
6. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

168

Key exclusion criteria

1. Pre-existing diabetes
2. History of cardiovascular disease (CVD) including hypercholesterolaemia, hypertension
3. On other medications that may have an effect on blood lipid profiles (besides routine HIV prophylaxis and tuberculosis [TB] treatment)
4. CD4 count < 50
5. Unable to tolerate solid foods
6. Failed appetite test
7. Subjects with pacemakers or any implantable electronic devices
8. Pregnancy or lactation
9. Psychiatric illness
10. Nut allergies
11. Consent declined
12. Any other reason why the consenting investigator thinks it is not appropriate for them to take part

Date of first enrolment

26/01/2009

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

Zambia

Study participating centre
Valid International/ Nutrition
Lusaka
Zambia
P.O. Box 50719

Sponsor information

Organisation
Valid International (UK)

Sponsor details
35 Leopold St
Oxford
United Kingdom
OX4 1TW

Sponsor type
Research organisation

Website
<http://www.validinternational.org>

ROR
<https://ror.org/00sb6vz77>

Funder(s)

Funder type
Research organisation

Funder Name
Valid international (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