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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/03/2009	**Overall study status** Completed	
Last Edited 24/03/2009	**Condition category** Infections and Infestations	

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
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/m^2
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 hypercholestrolaemia, 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
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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