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The role of nutritional support of human immunodeficiency virus (HIV) infected patients on antiretroviral treatment

Submission date
13/07/2010

Recruitment status
No longer recruiting

Registration date
04/10/2010

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
HIV infection can make it difficult for the body to absorb nutrients properly and the diet of a HIV patient with poor access to food will often be grossly inadequate. It is likely that the weight loss during disease is largely due to loss of lean body mass (muscle and organ tissues), but weight gain during recovery and after initiation of medical HIV treatment (ART) is mainly due to accumulation of fat. This is likely to have a negative impact on the health and survival of the HIV infected patient, particularly when quality of the diet is poor. It is possible that milk components as part of nutritional support could improve weight gain, growth, and recovery from malnutrition, but this needs to be confirmed. However, it is not clear whether nutritional support would work best and be safest when given from the beginning of ART, or whether it should be delayed until the acute stage of the infection and the side effects accompanying initiation of ART (such as anorexia and reduced absorption of nutrients) have declined. The aim of this study is to look at the effect of a whey-containing nutritional supplement on adult HIV patients starting ART in Jimma, Ethiopia. The protein source in the supplement will be either whey or soy. All participants will receive a peanut-based food supplement covering half of their daily energy need for three months. Since the optimal timing of nutritional support is unknown, patients who are not severely malnourished will receive the supplement either in the first three or the subsequent three months on ART.

Who can participate?
The study will be conducted among 350 HIV patients. Adults (≥18 years) initiating ART can participate in the study. Severely wasted individuals (body mass index<16 kg/m2) are excluded and referred for routine treatment for severe acute malnutrition at the hospital.

What does the study involve?
Patients are invited to take a peanut butter-based nutrient supplement daily for three months either during the first three or the subsequent three months upon initiation of ART. The supplement will have either whey or soy as the main protein source. Participants will be randomly selected to receive their 3 month supply of supplement either immediately, or after a three month delay. Each participant will be examined monthly during the first 6 months,

followed by a final examination 12 months after starting ART. The supplement is distributed from the research clinic at each monthly visit. Quality of life will be assessed and compared between the treatment groups using a questionnaire tool developed by the World Health Organisation (WHO) adapted to local context. Body composition will be assessed at the beginning of the trial and after 3 and 6 months. Grip strength will be measured, and physical activity will be assessed using the ActiHeart, a small combined accelerometer and heart rate monitor. Finally, blood samples will be taken from participants.

What are the possible benefits and risks of participating?
All patients will benefit from three months of daily supplementation with a high energy dietary supplement with high quality proteins of different origin. There are no known risks of the supplement. As the patients have HIV, they are already at high risk of disease and death, but the supplements are not expected to increase these risks.

Where is the study run from?
Jimma University Hospital, Ethiopia.

When is the study starting and how long is it expected to run for?
Recruitment began in July 2010 and ended in August 2012. Each participant is in the study for 12 months. The last 12-month follow-up visit will be conducted in August 2013.

Who is funding the study?
US Dairy export council (USDEC) and Danish International Development Agency (DANIDA)

Who is the main contact?
Dr Pernille Kæstel
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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
The role of nutritional support of human immunodeficiency virus (HIV) infected patients on antiretroviral treatment: a randomised trial in Jimma, Ethiopia

Acronym
ARTFOOD

Study objectives
Ready-to-use supplementary foods (RUSF) given to human immunodeficiency virus (HIV) patients during the first three months of antiretroviral therapy (ART) increases lean body mass and physical performance, and the effect is larger if the supplement contains whey protein rather than soy.

On 10/01/2013 the following changes were made to the record:
1. The target number of participants was updated from 400 to 350.
2. The overall trial end date was updated from 31/12/2011 to 30/08/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethiopia: National Health Research Ethics Review Committee, 09/12/2009, ref: RDHE/30-90 /2009
2. Denmark: Danish National Committee on Biomedical Research Ethics, 16/01/2009, ref: 2008-7041-137/sumih

Study design
Randomised single-blind nutritional supplementation trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Human immunodeficiency virus (HIV) infection

Interventions
200 g per day of a RUSF containing whey or soy protein for three months from the start of ART, or no supplement for the first three months, but the same supplement from three to six months after the start of ART.

Total duration of treatment: 3 months
Total duration of follow-up: 12 months

Intervention Type
Supplement

Primary outcome measure
Change over the first three months in:
1. Lean body mass as assessed using deuterium dilution test
2. Grip strength as assessed using a dynamometer
3. Physical activity assessed using a combined accelerometer and heart rate monitor

Secondary outcome measures
Measured after three months:
1. ART drug levels
2. HIV load and CD4 counts
3. Adherence to ART and quality of life
4. IGF-1

Overall study start date
19/07/2010

Completion date
30/08/2013

Eligibility

Key inclusion criteria
1. HIV-infected adults (aged greater than or equal to 18 years, either sex) commencing ART
2. Living within approximately 50 km from Jimma
3. Consenting to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Pregnant or lactating
2. Terminally ill from HIV or other serious condition
3. Patients who may not be able to consume RUSF due to extensive oral lesion
4. Patients with nutritional oedema

Date of first enrolment
19/07/2010

Date of final enrolment
30/08/2012

Locations

Countries of recruitment
Denmark

Ethiopia

Study participating centre
University of Copenhagen
Frederiksberg C
Denmark
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Sponsor information

Organisation
University of Copenhagen (Denmark)

Sponsor details
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Sponsor type
University/education

Website
http://www.ku.dk/english/

ROR
https://ror.org/035b05819

Funder(s)

Funder type
Government

Funder Name
US Dairy Export Council (USDEC) (USA)

Funder Name
Danida (Denmark)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/04/2014		Yes	No
Results article	results	15/05/2014		Yes	No