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Effect of conjugated linoleic acid on body fat in men with HIV receiving antiretroviral therapy

Submission date
26/01/2015

Recruitment status
No longer recruiting

Registration date
10/03/2015

Overall study status
Completed

Last Edited
05/10/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The use of HAART in human immunodeficiency virus (HIV) management may lead to the development of HIV-associated lipodystrophy syndrome (HALS), characterised by abnormal body fat distribution (fat gain on the abdomen and fat loss from the face, arms and legs), high plasma triglycerides, high blood pressure and blood vessel dysfunction. HALS increases the risk of premature heart disease. Up to 85% of patients with HALS report that body shape changes have been noticed by friends, family or work colleagues. HALS has been shown to adversely affect quality of life and may cause stigma, low self-esteem, anxiety and depression. CLA is a fatty acid found naturally in milk and dairy products. HALS has been suggested to occur as a result of antiretroviral drugs altering the ability of fat cells to store fat. When fat cells in the face, arms and legs no longer store fat correctly, this fat leaks from fat cells and is taken up by fat cells in the abdomen. Recent research has shown that CLA is able to increase fat storage and improve fat cell function. The aim of this study is to investigate the effects of CLA on abdominal fat.

Who can participate?
Men with HIV who are receiving HAART and have a waist circumference greater than 94 cm (37 inches) or body mass index greater than 25 kg/m2

What does the study involve?
Participants are randomly allocated to one of two groups to take either CLA or placebo (sunflower oil) for 12 weeks.

What are the possible benefits and risks of participating?
A benefit is that the findings of this study will help identify whether CLA can reduce waist circumference and improve body fat abnormalities in men with HIV.

Where is the study run from?
St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2014 to April 2014

Who is funding the study?
King's College London (UK)

Who is the main contact?
Dr Cathriona Loonam

Contact information

Type(s)
Public

Contact name
Dr Cathriona Loonam

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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RJ113/N295

Study information

Scientific Title

Effects of a novel dairy fat (Conjugated Linoleic Acid) on body fat in men with HIV receiving highly active Anti-Retroviral Therapy (CLAART): a randomised controlled study

Acronym
CLAART

Study objectives
Conjugated linoleic acid (CLA) will reduce waist circumference in HIV-infected men receiving highly active antiretrovial therapy (HAART).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen Square Ethics Committee (UK), 12/09/2013, ref: 13/LO/1145

Study design
Double-blind randomised placebo-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 to request a patient information sheet

Health condition(s) or problem(s) studied
HIV-associated lipodystrophy

Interventions
1. Treatment arm: 3 g/day of mixed CLA isomers (cis9,trans11 and trans10,cis12; Clarinol A80)
2. Placebo: 3 g/day of high oleic sunflower oil

Intervention Type
Supplement

Primary outcome measure
Change in waist circumference: taken as the midpoint between the lowest rib and the right ilium at the mid-axillary line and measured at baseline, 6 weeks and 12 weeks

Secondary outcome measures

Measured at baseline, week 6 and week 12:
1. Body-mass index (weight and height measured using a Seca scale and stadiometer)
2. Body composition using Tanita bioelectrical impedance analyser (model TBF 300MA)
3. Body fat measured using skinfold caliper (Holtain)
4. 24-hour recall (using multiple pass 24-hour recall technique)
5. Liver function, plasma lipids and plasma glucose

Measured at week 6 and week 12 only:
1. Food frequency questionnaire (using the previously validated EPIC)
2. Physical activity questionnaire (using the the International Physical Activity Questionnaire - Short Form)

Measured at baseline and week 12 only:
1. Plasma CLA levels (measured using gas chromatography)
2. Oxidative stress (measured using a 2-thiobarbituric acid reactive substances assay)
3. Adipocytokines (measured using a cytokine and growth factor array cytokine chip array kit)
4. CD4 count (measured using flow cytometry)
5. HIV viral load determined by reverse-transcriptase polymerase chain reactoRT-PCR using the COBAS® AmpliPrep/COBAS® Taqman® HIV-1 Test v2.0 (Roche Diagnostics, Mannheim, Germany)

Overall study start date
12/02/2013

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. HIV positive
2. Age 18–55 years
3. On HAART
4. Waist circumference greater than >94 cm (37 inches) or ethnic-specific cutoff)
5. Overweight (body mass index > 25kg/m2)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
60

Total final enrolment
5

Key exclusion criteria
1. Current AIDS-defining illness
2. Any acute/chronic condition that might affect the interpretation of the results or the participant's ability to follow protocol correctly
3. Fasting hypertriglyceridaemia (> 1.7 mmol/L)
4. Fasting hyperglycaemia (> 7mmol/L)
5. Male subjects on testosterone replacement therapy
6. Use of any medication designed to reduce weight/body fat
7. Participants following a diet (self-prescibed or practitioner-prescribed) to reduce weight/body fat
8. Use of fat-based supplements (e.g., fish oils) in the previous 3 months
9. Known hypersensitivity to the investigational products according to the participant and medical notes

Date of first enrolment
17/01/2014

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
Department of Infectious Diseases
Harrison Wing
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

Sponsor details

Room 1.8 Hodgkin Building
Guy's Campus
King's College London
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England
United Kingdom
SE1 4UL

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
Guy’s and St Thomas’ NHS Foundation Trust

Sponsor details
16th Floor
Tower Wing
Guy’s Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
Collegium Regale Londiniense, King's, KCL

Funding Body Type

Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Due to the small sample size, it was difficult to conduct any meaningful statistical analysis on data gathered as part of the study. Therefore, the data from this study will not be published.

2015 results in thesis https://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.677153

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No