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Best Foods For your heart trial: dietary intervention to reduce cardiovascular risk in HIV dyslipidaemia

Submission date
08/08/2013

Recruitment status
No longer recruiting

Registration date
08/08/2013

Overall study status
Completed

Last Edited
14/10/2020

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Successful treatment for HIV has lead to an ageing HIV-positive population with heart disease as the most common cause of death. The underlying cause of the increased risk of heart disease observed in HIV is not understood, and cannot be explained by traditional risk factors. Lifestyle intervention is recommended, with a low-fat diet to promote cholesterol reduction. The addition of functional foods (such as plant stanols and nuts) produces more dramatic reductions in cholesterol. This is based on evidence from the general population. This study will find out if the Ultimate Cholesterol Lowering Plan (UCLP) will have a similar effect in people who have raised cholesterol due to their HIV infection and treatment.

Who can participate?
Adults with HIV infection on stable antiretroviral therapy and raised cholesterol can take part in this study.

What does the study involve?
Participants will be randomly allocated to receive dietary advice on either reducing saturated fat alone, or together with increasing intake of nuts, plant stanols, soya protein, olive oil, beans and oats (components of the UCLP), delivered for 6 months. Results from blood tests, questionnaires and interviews will assess the impact of the UCLP on the risk of heart disease in adults with HIV infection on antiretroviral therapy.

What are the possible benefits and risks of participating?
If this diet can significantly reduce blood cholesterol levels, patients may reduce their risk of a heart attack. Risks to participants are not expected in this study. Potential malabsorption of fat soluble vitamins will be monitored. Participants will be directed to their doctor in the case of any health concerns arising during the study.

Where is the study run from?
The study is run from the Heart of England NHS Foundation Trust (UK), University Hospital Birmingham (UK) and Coventry and Warwickshire Partnership NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The study starts in September 2013 and is expected to run until September 2016.

Who is funding the study?
National Institute for Health research (NIHR) (UK)

Who is the main contact?
Mrs Clare Stradling
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14823

Study information

Scientific Title
A randomised controlled pilot study to assess the feasibility of the ultimate cholesterol lowering plan dietary intervention for cardiovascular risk reduction in HIV dyslipidaemia

Acronym
BFF Trial

Study objectives

To test the feasibility and acceptability of the ultimate cholesterol lowering plan (UCLP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull Research Ethics Committee, 24/06/2013, ref: 13/WM/0225

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
Dietary intervention:
Diet 1: low saturated fat
Diet 2: low saturated fat, Ultimate Cholesterol Lowering Plan within Mediterranean style diet
The intervention is for 6 months, the follow up is for 12 months.

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability of trial procedures for recruitment, allocation, retention and the intervention. They will be measured at baseline, 6 and 12 months. Method used to measure these outcomes: recruitment rate, attrition rate, process evaluation questionnaires and qualitative interviews, compliance rate of participation, adherence to dietary intervention using food diaries and 5 question compliance score.

Secondary outcome measures
1. Difference in LDL-cholesterol between groups at 6 months
2. Estimates of variability and effect size for waist circumference, arterial stiffness, and other cardiovascular risk factors

Overall study start date
02/09/2013

Completion date
02/09/2016

Eligibility

Key inclusion criteria
1. Aged 18 years of age with stable HIV infection
2. On antiretroviral therapy for more than 6 months
3. Low Density Lipoprotein (LDL)-cholesterol >3mmol/l
4. Willing to make dietary changes
5. Able to give informed consent
Target Gender: Male & Female; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
60

Key exclusion criteria
1. Current opportunistic infection or recent weight loss in last 3 months
2. Pregnancy, or planning pregnancy in the next 6 months
3. Diagnosis of familial hyperlipidaemia (LDL-cholesterol >6mmol/l and family history)
4. Secondary causes of hypercholesterolemia
5. Renal or liver disease, diabetes, hypothyroidism (unless treated and on a stable dose of L-thyroxine)
6. Gross xanthoma, as this may predispose to hyper-absorption of plant sterols
7. Blood triglyceride level >10mmol/l, as this constitutes risk of pancreatitis
8. Nut allergy
9. Current use of lipid lowering agents, or any other interfering drug/diet
10. Cannot read and write in English, or inability to understand the printed materials
11. Any unstable psychiatric disorder, including known eating disorders
12. Current participation in a weight loss programme or other dietary intervention

Date of first enrolment

02/09/2013

Date of final enrolment
02/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Heartlands Hospital
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name

NIHR Doctoral Research Fellowship, UK; Grant Codes: NIHR-DRF-2012-05-204

Results and Publications

Publication and dissemination plan

08/06/2018: Results presented at Conference on Retroviruses and Opportunistic Infections (CROI) 2018: http://www.croiconference.org/sessions/mediterranean-portfolio-diet-hiv-dyslipidaemia-randomized-controlled-trial

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?
Protocol article	protocol	08/02/2016		Yes	No
Results article	results	01/03/2021	14/10/2020	Yes	No
HRA research summary			28/06/2023	No	No