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Differences in levels of heart fat in people living with HIV and the general population

Submission date 01/02/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/02/2024	**Overall study status** Completed	
Last Edited 16/02/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
The present study is designed to investigate differences between people living with HIV (PLWHIV) and general populations in terms of how the body uses and stores energy. Magnetic Resonance Imaging (MRI) is the primary tool employed to measure fat around body organs, including the heart and liver. The fat around body organs, also known as visceral fat, is known to be associated with metabolic syndrome and a risk factor for developing heart attacks and strokes. MRI scans are used frequently in hospitals to diagnose a range of conditions. These scans use radio waves to measure protons in body tissues. The machines can reconstruct tissues using complex algorithms to form composite images of body structures. Medical professionals commonly use MRI scans to evaluate the structure and function of the heart. Specific MRI sequences are employed to assess the integrity of heart muscle, establishing heart MRI as the gold standard imaging technique for heart and heart muscle disease assessment.

In this sub-study, multiple MRI sequences are used to evaluate both the heart and the liver, aiming to identify any changes in their respective fat levels. Furthermore, the study investigates alterations in fat levels within the heart muscle cells while concurrently assessing any changes in the heart's functionality. Individuals living with HIV are noted to have a roughly double risk of heart attacks compared to the general population. Previous studies demonstrate that this elevated risk may be attributed to the unique ways in which fat is stored and metabolized in the bodies of PLWHIV. The anticipation is that this study will provide valuable insights into the reasons behind the increased risk of heart attacks in HIV-positive individuals and shed light on how reducing visceral fat may mitigate this risk. The findings of this study may potentially pave the way for the development of new medicines or treatment strategies aimed at reducing the risk of heart attacks in individuals living with HIV.

Who can participate?
PLWHIV aged 40 years and over

What does the study involve?
This sub-study will use multiple MRI sequences to assess the heart and the liver to investigate any changes in heart and liver fat. In addition, any changes in fat levels within the heart muscle cells will be assessed whilst also looking for any change in the way the heart is functioning.

What are the possible benefits and risks of participating?
MRI scans do not use ionising radiation and there is no risk to undertaking an MRI in terms of radiation.

Where is the study run from?
University of Liverpool

When is the study starting and how long is it expected to run for?
April 2023 to March 2025

Who is funding the study?
British HIV Association

Who is the main contact?
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Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
337369

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 337369

Study information

Scientific Title
The association of ectopic fat and cardiovascular disease in people living with HIV and general populations: a cross-sectional analysis

Study objectives
A cross-sectional study was designed to assess the relationship between epicardial adipose tissue (EAT) volume and cardiovascular (CVD) risk in people living with HIV (PLWHIV) and general populations. Participants will be recruited from the regional HIV service hosted by Liverpool University Hospitals NHS Foundation Trust (LUHFT). HIV-negative / general population participants will be recruited from those undergoing CT Coronary Angiography.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending submission

Study design
Cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Epicardial adipose tissue (EAT) volume and cardiovascular (CVD) risk in people living with HIV and general populations

Interventions
Pre-screening. Participants will be approached for their interest to be involved in the study from routine clinics. If they are interested then a copy of the patient information leaflet will be provided and contact details passed to the study team. Details will be entered onto the screening log. Participants will be invited to a screening visit (visit 1) where we will take

informed written consent upon confirmation of eligibility. Participants will then undergo a brief medical history / focused examination, vital sign check, heart trace, height and weight check. They will then undergo a blood draw for the study bloods (approximately 30mls). In those that consent a subcutaneous fat biopsy will be taken from the gluteal area. All participants will have an ultrasound (FibroScan) of the liver. Participants will then have the MRI visit booked (tolerance 6 weeks from visit 1). Participants will be required to fill in the MRI safety form upon arrival and will undergo a non-contrast MRI (no cannula required). This will take approximately 45-60 minutes. The participant exits the study upon completion of the MRI. Particpants will be contacted at 5 years by a member of the study team to check for cardiovascular events.

Intervention Type
Other

Primary outcome(s)
Epicardial adipose tissue (mls) measured using cardiac MRI at MRI study visit

Key secondary outcome(s))
1. Intramyocardial triglyceride concentration (ppm) measured using MR spectroscopy at the MRI study visit
2. Fatty liver (KPa) measured using Fibroscan at screening visit (visit 1)
3. LV ejection fraction (%) measured using cardiac MIR at MRI study visit
4. T1 mapping (ms) measured at cardiac MRI at MRI study visit
5. T2 mapping (ms) measured at cardiac MRI at MRI study visit
6. Left atrial size (mls) measured at cardiac MRI at MRI study visit
7. LV mass (grams) measured at cardiac MRI at MRI study visit
8. Lipid profile (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglyceride (mmol/L)) measured at screening visit (visit 1)
9. HBA1c (mmol/mol) measured at screening visit (visit 1)
10. Adiponectin (ug/ml) measured at screening visit (visit 1)
11. Glucose (mmol/L) measured at screening visit (visit 1)
12. Insulin (IU/ml) measured at screening visit (visit 1)
13. HS-CRP (mg/dl) measured at screening visit (visit 1)
14. Leptin (ng/ml) measured at screening visit (visit 1)
15. Follow up 5 year data measured at 5 year telephone follow up

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. >40 years old
2. HIV-positive
3. Stable ART for >6 months with two VL <40 copies/ml based on local testing protocols
4. CD4 count >200cells/mm3 for >2 years from recruitment
5. Understand the study procedures, be able to comply with study procedures and voluntarily agree to participate by giving informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex
All

Key exclusion criteria
1. Subjects unable to comply with the study protocol
2. History of severe renal impairment (eGFR <30ml/min)
3. History of severe hepatic impairment (Child-Pugh Score >9)
4. Active hepatitis B or hepatitis C
5. Any active illness, which in the opinion of the investigator precludes participation in the study
6. History of cancer
7. Active illicit intravenous drug use
8. Investigators may decide the subject cannot proceed if there are any relevant other abnormal results in screening assessments
9. History or current GLP-1 agonist use
10. For female subjects: pregnancy or breastfeeding at screening.
11. Subjects currently taking: Atypical antipsychotics, omega 3 supplements, Telmisartan /Irbesartan, Thiazolidinediones or regular NSAID use
12. Familial hypercholesterolaemia

Date of first enrolment
01/03/2024

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research organisation

Funder Name
British HIV Association

Alternative Name(s)
British HIV Association (BHIVA)., BHIVA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	09/02/2024	16/02/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes