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The CASBAH Study

Submission date
17/12/2025

Recruitment status
Recruiting

Registration date
11/03/2026

Overall study status
Ongoing

Last Edited
11/03/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
HIV treatment with antiretroviral therapy (ART) works very well to keep the virus under control, but it does not cure HIV. People need to take ART every day for life because the virus can hide in certain cells and return if treatment stops. Researchers are looking for new ways to control HIV without daily tablets. One option is using special proteins called broadly neutralising antibodies (bNAbs), which can fight HIV in different ways. Early studies show that a single infusion of these antibodies can keep HIV levels low in the blood for months, but we do not know if they also protect the brain and spinal fluid. This study will find out if bNAbs can stop HIV from multiplying in these areas, which could help prevent brain damage and offer a new treatment approach.

Who can participate?
People with HIV who are already taking part in other research studies where they have stopped daily ART and may be receiving bNAbs.

What does the study involve?
Including screening, participants will attend four visits over about a year. Two visits will be at their usual research department and will include questions about brain health, memory and thinking tests, a questionnaire, blood samples, and a lumbar puncture (spinal tap). One visit will be to an imaging centre for a brain MRI scan. The final visit will be either in person or by phone.

What are the possible benefits and risks of participating?
The study may help researchers learn more about new HIV treatments, but it is unlikely to benefit participants directly. Risks include discomfort or side effects from procedures such as blood tests, lumbar puncture, and MRI scans. These will be explained in detail before joining.

Where is the study run from?
St Mary's Hospital, London (UK).

When is the study starting and how long is it expected to run for?
January 2026 to February 2028

Who is funding the study?
The U.S. Army Medical Research Acquisition Activity.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
361365

Central Portfolio Management System (CPMS)
71848

Grant code
HT94252430004

Study information

Scientific Title
Central Nervous System Health of Broadly Neutralising Antibodies and Interruption of Antiretroviral Therapy in Persons with HIV

Acronym
CASBAH

Study objectives
Study aim - To assess parameters of brain health in persons with HIV who have stopped daily oral antiretroviral therapy, with or without the administration of broadly neutralising antibodies (bNAb).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/12/2025, North West - Haydock Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; -; haydock.rec@hra.nhs.uk), ref: 25/NW/0367

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human immunodeficiency virus [HIV] disease

Interventions
This is a prospective, observational, single-centre clinical study.

Twenty (20) persons with HIV, who have stopped daily oral antiretroviral therapy and are participating in a clinical trial which involves the administration of bNAbs, will be enrolled.

Potentially eligible participants will be asked to provide their informed consent and attend their routine research clinic for a Screening visit. At this visit, potential participants will:
Be asked some questions about themself, their physical and mental health and any medications they take or have taken in the past.
If it has not been recorded recently via their parent bNAb study, their height, weight and blood pressure will be measured.
They will have a physical examination if they are experiencing any symptoms.
They will be asked some questions about their brain health.
They will complete some brain function (cognitive) tests.

They will complete a questionnaire about their mental and emotional health and wellbeing.
If they haven't had their HIV viral load measured within the last 4 weeks, blood will be collected to measure this at this visit.

Following the Screening visit, eligible participants will return for a follow-up visit, which consists of 2 parts - brain imaging and lumbar puncture examination. These visits can be done on the same day or within 30 days of each other. These visits should take place within 12 months of the Screening visit.

The first part will take place at an imaging facility, which is in a different location from their routine research clinic. They will have an MRI (magnetic resonance imaging) brain scan and have a blood sample collected.

Following this, they will attend their routine research clinic, where:
They will be asked some questions about their brain health.
They will complete some brain function (cognitive) tests.
They will complete a questionnaire about their mental and emotional health and wellbeing.
They will have another blood sample collected.
They will undergo a lumbar puncture examination and have some cerebrospinal fluid (CSF) collected.

Individuals may participate in the study on more than one occasion if their health circumstances relating to the primary endpoint assessment change.

Intervention Type
Other

Primary outcome(s)
1. Cerebrospinal fluid HIV RNA measured using hospital laboratory CSF HIV RNA assay at a follow-up visit within 12 months of screening

Key secondary outcome(s))
1. Cerebrospinal fluid and plasma inflammatory markers measured using a research laboratory assay at a follow-up visit within 12 months of screening

2. Neuroimaging markers of inflammation and neuronal integrity measured using brain MRI at a follow-up visit within 12 months of screening

3. Cerebrospinal fluid pharmacokinetics of bNAbs measured using a research laboratory assay at a follow-up visit within 12 months of screening

4. Detailed clinical sequelae relevant to brain function measured using cognitive screening questions, Patient Health Questionnaire (PHQ-9) and CogniFit tests at a follow-up visit within 12 months of screening

Completion date
28/02/2028

Eligibility

Key inclusion criteria

1. Documented HIV-1 infection
2. Full capacity to provide signed informed consent
3. Participating in a clinical trial which involves the administration of bNAbs
4. Has received at least one infusion of a bNAb or placebo
5. Able to comply with the study procedures in the opinion of the investigator

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Cerebral infections (including AIDS defining illnesses)
2. Contraindication for MRI examination (e.g. claustrophobia, metal implants, physically unable to lie flat)
3. Contraindication to lumbar-puncture examination (at the discretion of the investigator)

Date of first enrolment
16/03/2026

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Clinical Imaging Facility (CIF) at Imperial College Healthcare NHS Trust
Hammersmith Hospital Campus, Du Cane Road

London
England
W12 0HS

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
U.S. Army Medical Research Acquisition Activity

Alternative Name(s)
United States Army Medical Research Acquisition Activity, US Army Medical Research Acquisition Activity, The U.S. Army Medical Research Acquisition Activity, USAMRAA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

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