ISRCTN51060377 https://doi.org/10.1186/ISRCTN51060377

Exploring the long-term safety of antiretroviral treatment interruptions as part of HIV cure and remission clinical trials

Submission date
02/11/2026

Recruitment status
Not yet recruiting

Registration date
13/11/2026

Overall study status
Ongoing

Last Edited
05/11/2026

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
Antiretroviral therapy (ART) can control HIV and improve health for people living with HIV but it cannot cure HIV. There are several strategies that are being investigated towards HIV cure or remission. The only way to see if any treatment is effective is to temporarily stop ART. This process is called an analytical treatment interruption (ATI).
In the past, people were not closely monitored during studies that involved an ATI and significant drops in CD4 counts (that are needed for immune function) were allowed before ART was restarted. This type of ATI has been associated with worse health outcomes.
To make ATIs safe, current studies choose participants at lower risk of complications. Participants are closely monitored during ATI with frequent blood tests. There are strict criteria for when ART should be restarted. However, the long-term health outcomes for these modern ATI trials are unknown.
The COAST study is looking at the long-term health and quality of life of people living with HIV who did or did not previously take part in modern ATI trials.

Who can participate?
1. People aged 18 years and over living with HIV who have taken part in a clinical trial that involved an analytical treatment interruption according to modern ATI consensus guidelines (ATI-group)
2. People aged 18 years and over living with HIV who have not taken part in a clinical trial that involved an analytical treatment interruption and are matched to the ATI participants (non-ATI group)

What does the study involve?
Part A: Retrospective data collection from clinical records with or without information regarding a participants time in an ATI trial obtained directly from the ATI study sponsor.
Part B: Additional data collection directly from participants with or without the completion of a series of quality of life questionnaires (electronic).
Data will be collected at COAST study entry and again every 2 years out to 10 years per participant (pending additional funding).

What are the possible benefits and risks of participating?
This study is purely observational with no intervention. Consent and study visits (for Part B) can be done remotely. There are no direct benefits or risks of taking part.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
December 2026 to October 2030

Who is funding the study?
1. ViiV Healthcare (UK)
2. St Mary's Development Trust (UK)
3. NIHR Imperial Biomedical Research Centre (UK)

Who is the main contact?
1. Dr Tamara Elliott, tamara.elliott04@imperial.ac.uk
2. Maathini Balachandran, m.balachandran@imperial.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Tamara Elliott

Contact details
Imperial College London
South Kensington Campus
Exhibition Road
London
United Kingdom
SW7 2AZ
+44 (0)2075947393
tamara.elliott04@imperial.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
357550

Study information

Scientific Title
Clinical outcomes after structured interruption of antiretroviral therapy

Acronym
COAST

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/10/2026, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 972 2503; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 26/NE/0164

Primary study design
Observational

Secondary study design
Case-control study

Study type(s)

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

Interventions
Observational study with data collection as a combination of:
1. Review of clinical records
2. Direct consultation with participants +/- completion of a series of quality of life questionnaires
3. Directly from original ATI study sponsors for information during the time a participant was in the clinical trial

Intervention Type
Other

Primary outcome(s)
1. Composite of major adverse cardiovascular events or cardiovascular death measured using clinical diagnoses recorded in clinical records at 2 years (initial analysis) and every 2 years out to 10 years pending additional funding

Key secondary outcome(s)

Completion date
31/10/2030

Eligibility

Key inclusion criteria
Cases (analytical treatment interruption [ATI]) cohort):
Any individual living with HIV who has taken part in a clinical trial that involved an analytical treatment interruption (ATI) according to modern ATI consensus guidelines

Controls (non-ATI cohort):
Any individual living with HIV who has not had an ATI as part of a clinical trial and matched to cases

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/12/2026

Date of final enrolment
31/10/2028

Locations

Countries of recruitment
United Kingdom

England

Scotland

Belgium

Denmark

Germany

Netherlands

Norway

South Africa

Spain

Thailand

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
Mortimer Market Centre
Mortimer Market
London
England
WC1E 6JB

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital

369 Fulham Road
London
England
SW10 9NH

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Study participating centre
North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
England
M8 5RB

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
England
W2 1BL

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Funder Name
ViiV Healthcare

Alternative Name(s)
ViiV Healthcare Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
St Mary's Development Trust

Funder Name
NIHR Imperial Biomedical Research Centre

Alternative Name(s)
NIHR Imperial BRC, Imperial Biomedical Research Centre, BRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available