

# Cabotegravir and rilpivirine real-world experience

<b>Submission date</b> 05/02/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/04/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The purpose of the CORAL study is to obtain real-world data on the uptake, acceptability, and effectiveness of injectable 2-monthly long-acting cabotegravir and rilpivirine delivered in NHS clinics. Recent clinical trials have shown that the injectable long-acting cabotegravir and rilpivirine is safe, well tolerated and effective in controlling HIV. However, clinical trials are highly controlled environments and don't always reflect what happens in the real world. Real-world data from NHS HIV clinics is needed to better understand the uptake of injectable HIV treatment, the effectiveness of the injectable treatment and whether injections will be received on time.

### Who can participate?

Individuals aged 16 years old and over who are receiving treatment with long-acting cabotegravir and rilpivirine; and individuals receiving oral HIV treatment can be part of the comparator group.

### What does the study involve?

If individuals provide their consent to participate, the staff members at their HIV clinic will complete a questionnaire with data on their gender, age, date of HIV diagnosis, routine blood results, medical treatment, and illnesses for up to the next 5 years. The data will be extracted from their medical records. Following this, every 6 months, data from their routine visits to the clinic, information on medical history, blood test results, treatment, and possible symptoms and illnesses relating to HIV or its treatment will be collected from their patient records.

The study will not test any drugs and will not interfere with any treatment the participants may receive at the clinic. Participants are consenting to allow the researchers to gather routinely collected information about them and their care.

Participants will be required to complete a questionnaire at the time of enrollment, and then after 6 and 12 months. The questionnaire will take a maximum of 30 minutes to complete. It can be completed online in the comfort of their own home or at the clinic. After the completion of each questionnaire, participants will be given a £20 shopping voucher as a thank you for their time and effort.

An additional sub-cohort of people with HIV who are either new to the CORAL study or exiting the CORAL main study, who have ever received a dose of long-acting cabotegravir and rilpivirine will be asked to provide consent for the collection of their routine clinical data.

What are the possible benefits and risks of taking part?

The study seeks to improve knowledge about long-acting antiretroviral treatment delivered through the NHS. Therefore, participation in the CORAL study does not include any additional risks.

Where is the study run from?

The study is being run by the University of Sussex and taking place in different UK HIV clinics.

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

January 2023 to December 2026. The first HIV clinic will start running the study in February 2024. Each HIV clinic will run the study for 2 years.

Who is funding the study?

The CORAL study has received funding from ViiV Healthcare LLC.

Who is the main contact for the study?

Please contact the study manager Dr Kate Alford - K.Alford@bsms.ac.uk or the chief investigator Dr Fiona Cresswell - F.Cresswell@bsms.ac.uk

### **Study website**

<https://www.bsms.ac.uk/research/global-health-and-infection/research-areas/coral-study.aspx>

## **Contact information**

### **Type(s)**

Public, Scientific

### **Contact name**

Dr Kate Alford

### **ORCID ID**

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### **Type(s)**

Principal Investigator

### **Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

323249

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

PF15151, IRAS 323249, CPMS 56893

## Study information

**Scientific Title**

A non-interventional, mixed-methods, prospective cohort study to characterise the real-world implementation, roll out, safety and patient experience of the long-acting injectable HIV treatment regimen of 2-monthly cabotegravir and rilpivirine

**Acronym**

CORAL (Cabotegravir and Rilpivirine Real wOrLd experience)

**Study objectives**

There are likely to be challenges in the implementation of long-acting (LA) cabotegravir+rilpivirine (CAB+RPV) as part of routine clinical care in real-world settings; characterising these barriers will aid the development of strategies to overcome them. However, high levels of effectiveness and acceptability will be demonstrated in those who do switch to LA CAB+RPV in a real-world setting.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 27/07/2023, Seasonal REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048129; seasonal.rec@hra.nhs.uk), ref: 23/LO/0534

**Study design**

Non-interventional prospective cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Home, Hospital, Internet/virtual

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

People living with HIV on injectable antiretroviral treatment (CAB+RPV)

### **Interventions**

Current interventions:

This is a 2-year study (with a 12-month recruitment and a 12-month follow-up period for each participant), two-arm, multi-centre, mixed methods study examining the real-world experiences of people living with HIV and receiving long-acting (LA) injectable cabotegravir and rilpivirine (CAB+RPV).

This is an observational study which includes completing some questionnaires. This study examines the adoption of LA CAB+RPV in different HIV services across the UK. Additionally, it will examine the acceptability, feasibility, fidelity and effectiveness of LA CAB+RPV. Participants are required to complete a health-related quality of life questionnaire (the HIVPROM) and a treatment experience and satisfaction questionnaire at three time points over the 1-year follow-up period (i.e., baseline, 6 months and 12 months (study end)). A sub-sample of participants, purposively selected to represent the population, will also be invited to share their experiences in an in-depth interview with a researcher, from 6 months onwards. Additionally, HIV clinical variables will be recorded from routine blood samples taken at each LA injectable appointment and information on injection schedule completion and reasons for any discontinuations will be captured from patients' medical records. All study activities will take place at the patient's HIV service with the support of a research nurse, however, participant questionnaires will be available to complete online and at home.

An additional sub-cohort called the CORAL-Light cohort will be recruited from those new to the CORAL study or exiting the main CORAL study. For these participants only routinely collected clinical data is collated, there are no procedures after provision of informed consent

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Previous interventions as of 08/04/2025:

This is a 2-year study (with a 12-month recruitment and a 12-month follow-up period for each participant), two-arm, multi-centre, mixed methods study examining the real-world experiences of people living with HIV and receiving long-acting (LA) injectable cabotegravir and rilpivirine (CAB+RPV).

This is an observational study which includes completing some questionnaires. This study examines the adoption of LA CAB+RPV in different HIV services across the UK. Additionally, it will examine the acceptability, feasibility, fidelity and effectiveness of LA CAB+RPV. Participants are required to complete a health-related quality of life questionnaire (the HIVPROM) and a treatment experience and satisfaction questionnaire at three time points over the 1-year follow-up period (i.e., baseline, 6 months and 12 months (study end)). A sub-sample of participants, purposively selected to represent the population, will also be invited to share their experiences in an in-depth interview with a researcher, from 6 months onwards. Additionally, HIV clinical variables will be recorded from routine blood samples taken at each LA injectable appointment and information on injection schedule completion and reasons for any discontinuations will be captured from patients' medical records. All study activities will take place at the patient's HIV service with the support of a research nurse, however, participant questionnaires will be available to complete online and at home.

## **Intervention Type**

Other

## **Primary outcome measure**

Adoption of LA CAB+RPV measured using data collected from patient medical records at the end of the study (2 years from site opening)

## **Secondary outcome measures**

1. Acceptability of LA CAB+RPV will be assessed based on:
  - 1.1. Findings from in-depth qualitative interviews and focus groups with patient participants and healthcare workers (HCWs)
  - 1.2. Comparison of patient-reported outcomes, measured using the patient-reported outcome measure for adults living with HIV (HIV PROM) and the treatment satisfaction and treatment preference questionnaire, at months 0, 6 and 12 post-switch to LA CAB+RPV
2. The feasibility of LA CAB+RPV will be assessed based on:
  - 2.1. Findings from in-depth qualitative interviews and focus groups with patient participants and HCWs
  - 2.2. Patient and HCW questionnaires, measured using the treatment satisfaction and treatment preference questionnaire at months 0, 6 and 12 post-switch to LA CAB+RPV (patient) and the HCW survey collected during the participant recruitment period (HCWs)
3. Fidelity will be assessed based on the below and measured using data collected from participant medical records:
  - 3.1. The proportion of injections delivered within the visit window
  - 3.2. Number of oral bridging courses per patient per year
  - 3.3. Fidelity to 2-monthly HIV viral load monitoring (+/- 2 weeks of target date)
4. Effectiveness assessed based on:
  - 4.1. The proportion of those who begin LA CAB+RPV who remain virologically suppressed at 12 months (by FDA snapshot algorithm and intention to treat approach), and the proportion of those on oral ART who remain virologically suppressed at 12 months after the baseline date measured using data collected from participant medical records
  - 4.2. The proportion of each group who have experienced virological failure at 12 months measured using data collected from participant medical records

4.3 The number of HIV-related medical events at 12 months measured using data collected from participant medical records

**Overall study start date**

01/01/2023

**Completion date**

31/12/2026

## **Eligibility**

**Key inclusion criteria**

1. Understand the participant information and the study requirements and has the capacity to consent
2. Willing to comply with study procedures
3. Age 16 years or above
4. Is a member of one of the following groups:
  - 4.1. LA group - PLWH who have been recently switched (within the prior 6 months) or are prospectively switched to LA CAB+RPV during the enrolment period. This includes those who have received LA CAB+RPV outside of BHIVA criteria or on compassionate grounds.
  - 4.2. Oral ART group - PLWH who are demographically similar but not eligible for LA CAB+RPV according to BHIVA eligibility criteria and who continue oral ART within the study period (e.g. those who are HBVcoreAb+ or who have an underlying drug resistance mutation that precludes use of LA CAB+RPV). The intervention group to the oral group will be matched 3:1 by calendar period and other key variables where possible.

(added 08/04/2025)

CORAL-Light sub-cohort:

Anyone >16 years old who has received one or more doses of LA CAB+RPV who is not in the main CORAL study cohort or exiting the main CORAL cohort

**Participant type(s)**

Patient, Health professional

**Age group**

Mixed

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

200 plus 350 participants recruited into the CORAL-Light sub-cohort

**Key exclusion criteria**

1. In the opinion of the investigator is unable or unwilling to comply with the study requirements
2. Aged < 16 years old

**Date of first enrolment**

12/02/2024

**Date of final enrolment**

30/06/2026

## **Locations**

**Countries of recruitment**

England

Scotland

United Kingdom

Wales

**Study participating centre**

**University Hospitals Sussex NHS Foundation Trust**

Worthing Hospital

Lyndhurst Road

Worthing

United Kingdom

BN11 2DH

**Study participating centre**

**NHS Lothian**

Waverley Gate

2-4 Waterloo Place

Edinburgh

United Kingdom

EH1 3EG

**Study participating centre**

**Cardiff and Vale University Hospitals NHS Foundation Trust**

Woodland House, Maes-y-Coed Road

Cardiff

United Kingdom

CF14 4HH

**Study participating centre**

**Central Manchester University Hospitals NHS Foundation Trust**

Trust Headquarters, Cobbett House

Manchester Royal Infirmary  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Oxford University Hospitals**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

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

**Study participating centre**  
**Guy's and St Thomas' NHS Foundation Trust**  
St Thomas' Hospital, Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

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

**Study participating centre**  
**North Bristol NHS Trust**  
Southmead Hospital



Southmead Road  
Westbury-on-trym  
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BS10 5NB

**Study participating centre**  
**The Newcastle upon Tyne Hospitals NHS Foundation Trust**  
Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

## **Sponsor information**

**Organisation**  
University of Sussex

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**Sponsor type**  
University/education

**Website**  
<https://www.sussex.ac.uk/>

**ROR**  
<https://ror.org/00ayhx656>

## **Funder(s)**

**Funder type**  
Industry

**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

## Results and Publications

**Publication and dissemination plan**

Study results will be published in high-impact peer-reviewed journals and will be presented at national and international meetings. Publication will be following internationally recognized scientific and ethical standards concerning publications and authorships. We will ensure that all relevant stakeholders receive information on study outcomes. Full anonymity of participants' details will be maintained throughout, and no individual patient data will be presented

**Intention to publish date**

01/07/2027

**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?
<a href="#">Protocol file</a>	version 2.0	28/06/2023	07/02/2024	No	No