ISRCTN11668233 https://doi.org/10.1186/ISRCTN11668233

Cabotegravir and rilpivirine real-world experience

Submission date	Recruitment status	[X] Prospectively registered
05/02/2024	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2025	Infections and Infestations	[X] 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

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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
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United Kingdom
OX3 9DU

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

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

Study participating centre
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L7 8XP

Study participating centre
North Bristol NHS Trust
Southmead Hospital

Southmead Road
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Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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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 data

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?
Protocol file	version 2.0	28/06/2023	07/02/2024	No	No