Patient characteristics, Adherence, and Clinical Outcomes among People Living with HIV (PLWH), Initiating Cabotegravir + Rilpivirine LA Regimen in the OPERA Cohort

First published: 04/01/2025

Last updated: 03/07/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000427

Study ID

1000000427

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is an observational cohort study utilizing prospectively collected electronic health record (EHR) data obtained from the Observational Pharmaco-Epidemiology Research and Analysis (OPERA®) Database to assess the utilization patterns, durability, adherence and discontinuation, virologic effectiveness and safety of Cabotegravir (CAB) + Rilpivirine (RPV) Long Acting (LA) Regimen among adult PLWH. OPERA is a registered trademark of Epividian, Healthcare Analytics and Software firm

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-globalmailbox@gsk.com

Study contact

RD.CTT-globalmailbox@gsk.com

Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/12/2020

Actual: 17/12/2020

Study start date

Planned: 14/06/2021

Actual: 17/08/2021

Date of final study report

Planned: 31/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

OPERA_CAB+RPV LA Usage and Clinical Outcomes_Protocol Amendment 3 Anonymised 26 Jun 2025.pdf (823.44 KB)

OPERA_CABENUVA Usage and Clinical Outcomes_Protocol Amendment 1 Anonymised 15 Oct 2024.pdf (688.62 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is an observational study utilizing prospectively collected electronic health record (EHR) data obtained from the OPERA® cohort.

Main study objective:

To assess the utilization patterns, durability, adherence and discontinuation, virologic effectiveness and safety of Cabotegravir (CAB) + Rilpivirine (RPV) Long Acting (LA) Regimen among adult PLWH.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

CABENUVA

Study drug International non-proprietary name (INN) or common name

CABOTEGRAVIR

RILPIVIRINE

Anatomical Therapeutic Chemical (ATC) code

(J05AG05) rilpivirine

rilpivirine

(J05AJ04) cabotegravir

cabotegravir

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

The study population will include treatment experienced PWH who are 18 years or older, are active in care in OPERA, and received at least one CAB+RPV LA injection between 21JAN2021 and 31DEC2023, 21JAN2021 and 31DEC2024, and 21JAN2021 and 31DEC2025. PWH will be followed from the date of their first CAB+RPV injection until discontinuation of CAB+RPV regimen, death, loss to follow-up (12 months after last clinical contact), or study end (29FEB2024, 28FEB2025, and 28FEB2026).

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 65 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

4000

Study design details

Outcomes

• To describe demographics, clinical characteristics, patterns of use, persistence, adherence, discontinuation, virologic effectiveness and factors associated with confirmed virologic failure among PWH receiving CAB+RPV LA at Year 3, Year 4, and Year 5 of availability.

• Sub-group analyses by viral load, BMI and age at initiation to assess characteristics, adherence, persistence, discontinuation and virologic effectiveness.

• To estimate the frequency of documented injection site reactions and hypersensitivity reactions among PWH receiving CAB+RPV LA injections at Year 3, Year 4, and Year 5 of availability.

• To compare baseline characteristics and treatment outcomes (persistence/discontinuation, adherence, maintaining virologic suppression, confirmed virologic failure) between oral ART and CAB+RPV LA use in PWH at Year 4 and Year 5 of availability

• To describe baseline characteristics and treatment outcomes (persistence/discontinuation, adherence, virologic effectiveness) among PWH receiving CAB+RPV LA injections at Year 4 and Year 5, in subgroups of interest a) Race/ethnicity (Non-Hispanic Black, Hispanic, Non-Hispanic White) b) Sex/race (Non-Hispanic Black men, Hispanic men, Black women)

• Among individuals with confirmed virologic failure (CVF): to describe HIV resistance and proviral testing at the time of CVF, as well as history of resistance and proviral DNA testing prior to CVF at Year 4 and Year 5 of availability

• Among individuals with confirmed virologic failure (CVF): to describe the ART regimens after CVF in OPERA at Year 4 and Year 5 of availability a) To describe the baseline characteristics (demographic, clinical, treatment patterns) of ART regimen after CVF b) To describe virologic response (suppression, non-response, confirmed virologic failure) to ART regimen after CVF

Data analysis plan

Baseline characteristics and outcomes will be described using counts and relative frequencies for categorical variables and medians with interquartile ranges (IQR) for continuous variables. For outcomes assessed at any point during follow-up, incidence rates will be estimated using unadjusted Poisson regression, accounting for person-time since index (i.e., first CAB+RPV LA injection). Analyses will be stratified by viral load (<50 copies/mL vs. ≥ 50 copies/mL), BMI (<30 kg/m2 vs. ≥30 kg/m2) and age (<18, 18-50, 50-64, ≥65 years) at initiation of CAB+RPV regimen. Factors associated with confirmed virologic failure will be assessed using multiple logistic regression.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

OPERA Cohort

Data sources (types)

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No