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

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000427

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

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Institution

Contact details

Study institution contact

Call Center EU GSK Clinical Trials

Study contact

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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_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

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

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.

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 - <200 copies/mL vs. ≥200 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

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