Prospective Study to Assess Usage, Adherence, Effectiveness of Cabotegravir LA for Pre-Exposure Prophylaxis in the United States in the OPERA Cohort (219844)

First published: 17/05/2024

Last updated: 11/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000165

EU PAS number

EUPAS1000000165

Study ID

1000000165

DARWIN EU® study

No

Study countries

United States

Study description

This is an observational study utilizing prospectively collected electronic health record (EHR) data obtained from the Observational Pharmaco-Epidemiology Research and Analysis (OPERA) clinical cohort to describe the effectiveness, adherence, and usage of cabotegravir (CAB) LA for PrEP and monitor incidence of HIV and HIV treatment outcomes for cases of HIV acquisition among participants on CAB LA for PrEP in the United States.

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

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
Actual: 09/11/2022

Study start date
Actual: 20/07/2023

Date of final study report
Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

ApretudeUpdateOutcomes_OPERA_Final_Protocol_Anonymised.pdf(768.61 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a Cohort study.

Analyses will be conducted cumulatively at three time points through this study.

For each analysis, all primary/secondary objectives have specific follow-up periods.

Main study objective:
Description of effectiveness, adherence, and usage of cabotegravir (CAB) LA for PrEP and monitor incidence of HIV and HIV treatment outcomes for cases of HIV acquisition among participants on CAB LA for PrEP in the United States.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
APRETUDE

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

Anatomical Therapeutic Chemical (ATC) code
(J05AJ04) cabotegravir
cabotegravir

Medical condition to be studied
HIV infection

Population studied

Short description of the study population

This study includes adults and adolescents initiating a new PrEP formulation: either as oral PrEP or LA-PrEP.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

10000

Study design details

Outcomes

Primary Outcomes

- Number of participants with baseline characteristics including demographic and clinical characteristics of oral and LA PrEP users
- Adherence and usage patterns of CAB OLI and/or LA-PrEP, number of participants with HIV and STIs while on CAB OLI and/or LA PrEP
- Number of participants receiving HIV treatment and having virologic suppression after HIV acquisition

Secondary Outcomes

- Number of participants with incomplete initiation of CAB LA for PrEP

Data analysis plan

For Primary Objective 1, baseline characteristics will be described and statistical comparisons between PrEP type (CAB LA vs daily oral) will be conducted using chi-square tests for categorical variables and Wilcoxon-Mann-Whitney tests for continuous variables, as appropriate.

For Primary Objective 2, adherence and usage pattern outcomes will be described among CAB PrEP users.

For Primary Objective 3, incidence of STIs and HIV will be described as a frequency and an incidence rate among CAB PrEP users.

For Primary Objective 4, follow-up care and virologic outcomes will be described as median (IQR) values for continuous data and relative frequencies for categorical data among individuals who acquired HIV while on CAB PrEP.

For Secondary Objective 1, select baseline demographic and clinical characteristics and ISR will be assessed among individuals with only one injection (i.e., loading dose) who have sufficient follow-up after the loading dose to observe delayed or missed second doses.

Data management

Data sources

Data source(s), other

OPERA (Observational Pharmaco-Epidemiology Research & Analysis) Cohort

Data sources (types)

Electronic healthcare records (EHR)

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

Not applicable