CAB LA PrEP Cohort: Prospective Cohort Study to Assess Effectiveness and Safety of, and Adherence and Resistance to Cabotegravir for Pre-Exposure Prophylaxis in the United States (217671)

First published: 22/05/2024

Last updated: 05/06/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000163

EU PAS number

EUPAS1000000163

Study ID

1000000163

DARWIN EU® study

No

Study countries

United States

Study description

The study will aim to assess usage patterns, adherence, effectiveness, safety, and resistance among individuals initiating CAB LA for PrEP in real world clinical setting, 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: 09/07/2021

Study start date

Actual: 26/05/2022

Date of final study report

Planned: 22/05/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

CAB_LA_for_PrEP_Prospective_Cohort_Study_in_the_US_Final_Protocol_Anonymised.pdf

(650.79 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This will be a 5-year long prospective cohort study of adults and adolescents ≥35 kgs initiating CAB LA for PrEP in real-world clinical setting in the United States.

Main study objective:

Following the initiation of CAB LA for PrEP, the study will aim to assess usage patterns, adherence, effectiveness, safety, and resistance among individuals diagnosed with HIV infection.

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

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 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

0

Study design details

Outcomes

- Participants with incidence and diagnosis of HIV
- Participants receiving CAB LA PrEP with diagnosis of HIV
- Time to diagnosis of incident HIV
- CAB PrEP users receiving ART regimen and with VL testing for prevalent and incident HIV infections
- Participants with adherence to CAB LA PrEP, resistance to INSTIs and specific mutations, DILI, hypersensitivity reactions

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Data analysis plan

Descriptive analyses will summarize baseline characteristics of study participants and covariables will be reported as frequencies/median (IQR) at baseline and at follow-up. Time to HIV diagnosis will be assessed using Kaplan-Meier curve. Cox proportional hazards models will be constructed to compare time to HIV diagnosis adjusting for participant characteristics. Adherence will be estimated using the date of injections over 6 and 12-month periods. Frequency

of resistance will be described among individuals who acquire HIV infection while on CAB LA for PrEP.

Data management

Data sources

Data source(s), other

Trio Health HIV 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