CAB LA PrEP Cohort: Prospective Cohort Study to Assess Adherence and Effectiveness of, and Monitor for Hepatotoxicity and Resistance to, Cabotegravir for Pre-Exposure Prophylaxis in Europe (221935)

First published: 22/08/2024

Last updated: 11/11/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000299

Study ID

1000000299

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Ireland
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

This is a prospective observational cohort study. The study`s aim is to understand the population receiving CAB LA for PrEP in routine clinical practice, usage patterns, adherence, post marketing clinical effectiveness, discontinuations, and monitor for resistance among individuals who receive an HIV diagnosis while on CAB LA for PrEP.

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Networks

NEAT-ID Network

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: 02/08/2023

Actual: 27/11/2023

Study start date

Planned: 30/08/2024

Actual: 23/08/2024

Date of final study report

Planned: 30/06/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

221935_NEAT ID_CAB LA PrEP Cohort Study in Europe_Final Protocol Anonymised 12 Aug 2024.pdf(1.13 MB)

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:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe the population initiating CAB LA for PrEP and to monitor for adherence, HIV incidence, occurrence of drug-induced liver injury (DILI) and hypersensitivity reactions (HSRs) and risk of developing resistance while on CAB LA for PrEP.

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

Drug-induced liver injury

Drug hypersensitivity

Additional medical condition(s)

No particular condition

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

500

Study design details

Outcomes

Incident HIV diagnoses (frequency of diagnosis, proportion of CAB LA PrEP users with diagnosis, time to diagnosis, ART regimen and viral load testing after diagnosis); adherence and durability of regimen, resistance to specific mutations; DILI and HSRs.

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

Prospective patient-based data collection from participating European clinical sites within the NEAT-ID
Network

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