Frequency of HIV diagnoses among people using oral and LA PrEP (223555)

First published: 21/11/2024

Last updated: 09/09/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000371

Study ID

1000000371

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of the study is to understand patterns of PrEP use among people who acquire HIV to improve public health and clinical practice.

This study will also provide crucial real-world evidence on HIV acquisition on

PrEP, PrEP coverage, HIV testing and sexually transmitted infection (STI) screening in individuals receiving either oral or LA PrEP. Analysis is based on the OPERA cohort.

Study status

Finalised

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: 28/06/2024

Actual: 28/06/2024

Study start date

Planned: 06/12/2024

Actual: 22/11/2024

Date of final study report

Planned: 31/08/2026

Actual: 10/08/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

OPERA_CAB PrEP_Oral and LA PrEP HIV Diagnoses_Final Protocol Anonymised 23 Oct 2024.pdf (1.75 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A cohort study using secondary data from the OPERA (Observational PharmacoEpidemiology Research & Analysis) cohort

Main study objective:

To assess the annual incidence of HIV diagnoses among all people without HIV in current study.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

(Obj 1) People in OPERA aged ≥18 years with ≥1 clinical encounter during the calendar year of interest and no evidence of prior HIV diagnosis.
(Obj 1a) People with an incident HIV diagnosis identified in Obj 1.
(Obj 2-5) People without HIV in OPERA aged ≥18 years who initiated any new PrEP formulation during the study period with or without prior PrEP use.
(Obj 6) People without HIV in OPERA aged ≥18 years who could benefit from PrEP and are not on PrEP

Age groups

- 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

23.000

Study design details

Setting

OPERA is a multi-site observational database collecting data prospectively from the complete electronic health records (EHR) from clinical care throughout the US.

Outcomes

- Annual number of new HIV diagnoses
- PrEP use, characteristics among people with an incident HIV diagnosis
- Characteristics of people who initiate oral and LA PrEP
- Incidence of HIV diagnoses following oral/LA PrEP initiation
- Days with an oral PrEP prescription and LA PrEP coverage
- Frequency of HIV testing and STI screening at oral/LA PrEP initiation
- Characteristics among people who could benefit from PrEP

Data analysis plan

The analysis will be performed on OPERA cohort using secondary data from electronic medical records.

Summary results

A total of 2,514 HIV acquisitions were recorded in the OPERA cohort, of whom only 12% had ever received PrEP and 10% had received PrEP within ≤30 days before the HIV diagnosis.

A total of 39,011 adults without evidence of HIV started a new PrEP formulation in OPERA and contributed a total of 41,105 episodes of PrEP use during the study period (39,193 oral PrEP episodes, 1,912 CAB LA PrEP episodes). A median of 93% of days followed were covered by CAB LA PrEP (IQR: 81, 100) compared to a median of 58%
of days followed covered by oral PrEP (IQR: 25, 94).
Within 12 months of start, there was one HIV acquisition on CAB LA PrEP, for an IR of 0.9 per 1000 person-years (95% CI: 0.1, 6.5), compared to 180 HIV acquisitions on oral PrEP, for an IR of 4.9 per 1000 person-years (95% CI: 4.3, 5.7). HIV testing occurred more frequently on CAB LA PrEP (IR: 6.51 per person-year; 95% CI: 6.38, 6.65) than oral PrEP (IR: 2.90 per person-year; 95% CI: 2.89, 2.92) over the first year of a PrEP episode. STI testing also occurred more frequently on CAB LA PrEP (IR: 5.09 per person-year; 95% CI: 4.97, 5.20) than oral PrEP (IR: 3.22 per person-year; 95% CI: 3.20, 3.24).
Between 21DEC2021 and 30JUN2024, there were 141,652 individuals who could benefit from PrEP in OPERA. Their rate of HIV diagnosis was 0.75 per 100 person-years (95% CI: 0.71, 0.80). The rate of HIV testing was 1.26 per person-year (95% CI: 1.26, 12.27). A third (35%) received ≥1 STI diagnosis. The rate of STI diagnosis was 41.64 per 100 person-years (95% CI: 41.30, 41.97). The rate of STI screening was 1.68 per person-year (95% CI: 1.68, 1.69).

Documents

Abstract of study report

Abstract-Anonymised 07 Sep 2026.pdf (221.03 KB)

Study report

OPERA_HIV Acquisition between Oral vs LA PrEP_Final Report-Anonymised 07 Sep 2026.pdf (2.69 MB)

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)

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

No