Comparison of Dolutegravir Effectiveness vs. Other Anchor Agent Effectiveness among Hepatitis C Virus Co-infected patients in the OPERA® Observational Database (207833)

First published: 14/07/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19875

Study ID

42158

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/04/2017

Actual: 04/04/2017

Study start date
Planned: 28/07/2017

Actual: 21/07/2017

Data analysis start date
Planned: 27/06/2017

Date of final study report
Planned: 24/10/2018

Actual: 14/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-207833-protocol-redact.pdf(2.46 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:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Observational cohort analysis

Data collection methods:

Secondary use of data

Main study objective:

To describe the baseline demographic and clinical characteristics, to estimate and compare the frequency of liver enzyme elevations by grade and discontinuation due to hepatotoxicity, and to describe and compare time to virologic suppression (<50 copies/ml) among HIV+/HCV+ patients initiating dolutegravir, darunavir, raltegravir, or elvitegravir</50></50>

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational analysis

Study drug and medical condition

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

DOLUTEGRAVIR

DARUNAVIR

RALTEGRAVIR

ELVITEGRAVIR

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

The study sample will be identified from the OPERA Database for analysis according to the inclusion criteria defined below.

Patients initiating an anchor-of-interest-based regimen between August 12, 2013 and June 30, 2016 will be included in the study sample if they meet the following inclusion criteria:

1) A diagnosis of HIV-1, a positive HIV-1 Western Blot, or a positive HIV-1 enzyme-linked immunosorbent assay (ELISA); and a detectable HIV-1 viral load test.

2) A diagnosis of HCV and PCR or serology positive.

3) At least 13 years of age at the index date.

4) At least one HIV-1 viral load test on or up to 120 days prior to index date.

5) Continuous clinical activity in the year following anchor-of-interest-based regimen initiation, defined as at least one clinical contact (visit or telephone contact)

Subjects with the following criteria will be excluded from the study sample:

1) HIV negative.

2) HCV negative.

3) A diagnosis of HIV-2, a positive HIV-1/HIV-2 Multispot, a positive HIV-2-specific ELISA, a positive HIV-2 Western Blot or a detectable HIV-2 viral load test.

4) Initial anchor-of-interest-based regimen treatment identified as a component of post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP).

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)

Special population of interest

Immunocompromised

Estimated number of subjects

815

Study design details

Outcomes

Incidence of viral suppression (viral load < 50 copies/mL) 12 months after regimen initiation, incidence of and time to liver enzyme elevations (grade 3 or higher) after regimen initiation, and incidence of discontinuation/switching due to hepatotoxicity

Data analysis plan

Descriptive statistics will be used to describe clinical and demographic patient characteristics of the overall HIV+/HCV+ population and those co-infected and initiating core-of-interest-based regimens. Clinical outcomes, including liver enzyme elevations (grading) and discontinuation due to hepatotoxicity, will be described using frequency distributions for categorical variables and medians with IQRs for continuous variables. Kaplan Meier methods and multivariable Cox proportional hazards models will be used to estimate and model time to virologic suppression in each group of patients by core-of-interest-based regimen prescribed.

Documents

Study results

viiv-207833-clinical-study-report-redact.pdf(5.21 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 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