A Comprehensive Assessment of Adverse Events and Overall Safety Profile in HIV Positive Patients Treated with Dolutegravir as Compared to Other Integrase Strand Transfer Inhibitors or Darunavir (207832)

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Study | Finalised

Administrative details

EU PAS number

EUPAS22231

Study ID

42164

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: 06/12/2017

Actual: 06/12/2017

Study start date
Planned: 08/01/2018

Actual: 12/01/2018

Date of final study report
Planned: 29/11/2019

Actual: 04/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-207832-protocol-redact.pdf (376.43 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

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 and to quantify and compare the prevalence and incidence of on-label potential and identified risks included in the Dolutegravir Risk Management Plan in HIV+

patients who initiated dolutegravir, elvitegravir or raltegravir as part of an ART regimen

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DOLUTEGRAVIR

ELVITEGRAVIR

RALTEGRAVIR

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

The study population consisted of HIV-positive patients at least 13 years of age initiating a core agent of interest prescribed by an OPERA caregiver during the eligibility period (August 1, 2013 to December 31, 2016).

The analysis population will be identified from the OPERA Observational Database

according to the inclusion criteria defined below.
Patients initiating any INSTI or DRV between August 01, 2013 and December 31, 2016:
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) At least 13 years of age at the index date.
3) ART naïve or experienced.
4) Initiation of DTG or EVG or RAL or DRV between August 01, 2013 and December 31, 2016.

Subjects with the following criteria will be excluded:
1) HIV negative
2) A diagnosis of HIV-2, a positive HIV-1/HIV-2 Multi-spot, a positive HIV-2-specific ELISA, a positive HIV-2 Western Blot or a detectable HIV-2 viral load test
3) Patients prescribed monotherapy regimens (includes 1 core agent with or without a PK boosting agent)
4) Patients prescribed PEP or 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

13.000

Study design details

Outcomes

Prevalence and incidence of risks/adverse events of interest detailed in the risk management plan and product label of dolutegravir

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Data analysis plan

Descriptive statistics will be used to summarize baseline demographics, clinical characteristics and adverse event history of HIV+ patients initiating an INSTI-based regimen. Adverse events diagnosed will be described as frequencies and classified by the system-organ-class (SOC) hierarchical categorization, and P-values will be calculated to evaluate differences between groups.

Documents

Study results

viiv-207832-clinical-study-report-redact.pdf (1.96 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