Descriptive Analysis of Neuropsychiatric Diagnoses in Patients taking Dolutegravir in the OPERA® Observational Database (205846)

First published: 17/05/2016

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13473

Study ID

42117

DARWIN EU® study

No

Study countries

☐ United States

Study description

A descriptive analysis of neuropsychiatric diagnoses made within a large, geographically-diverse, real-world clinical setting utilizing prospectively-collected electronic medical record (EMR) data obtained from the Observational Pharmaco-Epidemiology Research & Analysis (OPERA®) Observational Database

Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/04/2016

Actual: 07/04/2016

Study start date

Planned: 18/05/2016

Actual: 18/05/2016

Data analysis start date

Planned: 18/05/2016

Actual: 18/05/2016

Date of final study report

Planned: 01/06/2017

Actual: 29/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

gsk-205846-protocol-redact.pdf(54.39 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

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

Observational cohort analysis

Data collection methods:

Secondary use of data

Main study objective:

To summarize neuropsychiatric tolerability diagnoses in a population of HIV-positive males and females who have been prescribed DTG-based, EFV-based, RAL-based, DRV-based, Complera, and Stribild regimens including both antiretroviral (ART) naïve and ART experienced patients

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive analysis

Study drug and medical condition

Name of medicine

STRIBILD

Name of medicine, other

Complera

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

DOLUTEGRAVIR

EFAVIRENZ

RALTEGRAVIR

DARUNAVIR

ABACAVIR

LAMIVUDINE

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

HIV-positive patients who have been prescribed DTG-based, efavirenz (EFV)-based, ralutegravir (RAL)-based, or darunavir (DRV)-based regimens by an OPERA caregiver including both treatment naïve and treatment experienced patients.

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)

Special population of interest

Immunocompromised

Estimated number of subjects

2000

Study design details

Outcomes

Neuropsychiatric diagnoses of interest and time to discontinuation

Data analysis plan

Patient demographics, baseline clinical characteristics and neuropsychiatric diagnoses will be described using frequency distributions. Medians with interquartile ranges will be used to describe time to neuropsychiatric events. Frequency of events distributions will be generated for: DTG-based, EFV-based, RAL-based, DRV-based, Complera, and Stribild regimens. Comparison of demographics will be conducted for patients on DTG with and without neuropsychiatric events.

Documents

Study results

viiv-205846-clinical-study-report-redact.pdf(964.04 KB)

Data management

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