An Evaluation of Weight Gain in Patients Treated with Dolutegravir vs. Other Core Agents (208943)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42173

EU PAS number

EUPAS27523

Study ID

42173

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

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

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: 14/12/2017

Actual: 14/12/2017

Study start date
Planned: 18/01/2019

Actual: 18/01/2019

Data analysis start date
Actual: 01/05/2019

Date of final study report
Planned: 30/08/2019

Actual: 07/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-208943-protocol-redact.pdf(1.39 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:

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 BMI categories, weight, lipid levels, and lipodystrophy among new users of DTG and other INSTIs at core agent initiation and at 6, 12, and 24 months after core agent initiation (stratified by ART- naïve and ART experienced) and to estimate the association between specific core agent initiation and changes in BMI at 6, 12, and 24 months after core agent initiation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DOLUTEGRAVIR

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

The analysis population will be identified from the OPERA Observational Database according to the inclusion criteria defined below.

Primary population

1) A diagnosis of HIV-1, a positive HIV-1 Western Blot, or a positive HIV-1-specific ELISA; and a detectable HIV-1 viral load test

2) At least 18 years of age at the index date

3) Male or female patients

4) Prescribed DTG, RPV, RAL, BIC, EVG/c and DRV(/r/c) as part of a 3-drug regimen for the first time between 01AUG2013 and 31DEC2017

5) Not exposed to >1 core agent of interest concurrently

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

1) HIV-negative

2) 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

3) Women who are considered pregnant at the index date

4) Transgender patients (potential for weight changes due to hormone use)

Secondary population

The study population for the secondary objectives will be a subset of the primary study population meeting the following additional inclusion criteria:

1) Patients switching to DTG, RPV, RAL, BIC, EVG/c or DRV(/r/c) as part of a 3-drug regimen for the first time between 01AUG2013 and 31DEC2017 (excluding ARTnaïve patients)

2) Patients with a viral load <200 copies/mL at last viral load test prior to switch to core agent of interest

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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

15000

Study design details

Data analysis plan

Descriptive statistics will be used to summarize baseline demographic and clinical characteristics, as well as weight, lipid, and lipodystrophy outcomes at each time point (6,12, and 24 months). Pairwise comparisons will be made between DTG and other core agents. Adjusted linear regression models will be used to assess the association between core agent and mean changes in BMI at 6, 12, and 24 months. Baseline variables meeting the definition of a confounder will be included in the adjusted models, and will be selected a priori. The analysis will be stratified by baseline BMI categories (underweight, normal weight, overweight, obese).

Documents

Study results

viiv-208943-clinical-study-report-redact.pdf(5.71 MB)

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