An evaluation of weight gain in patients treated with dolutegravir and other core agents (209025)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42179

EU PAS number

EUPAS28753

Study ID

42179

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

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: 17/07/2018

Actual: 17/07/2018

Study start date
Planned: 21/03/2019

Actual: 08/03/2019

Data analysis start date
Actual: 10/04/2019

Date of final study report
Planned: 31/01/2020

Actual: 30/01/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

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 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:

Combined primary data collection and secondary use of data

Main study objective:

To describe the baseline demographic and clinical characteristics of ART-naïve and ART-experienced people living with HIV (PLWH) initiating DTG vs other core ART agents, and to quantify and compare rates between ART-naïve and ART-experienced patients initiating DTG vs. other core agents including change in weight and body mass index (BMI)

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

ART-naïve and ART-experienced people living with HIV (PLWH) initiating DTG vs other core ART agents.

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

A linear mixed models method with an unstructured or exchangeable correlation structure and robust standard errors to assess differences in BMI/weight associated with antiretroviral medications accounting for within-subject correlations between repeated measures and confounding covariates will be used

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Prospective patient-based data collection, CNICS - Prospectively collected electronic medical record data

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