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

First published: 05/03/2019

Last updated: 02/07/2024

Study Finalised

Administrative details

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

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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: 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 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:

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

15.000

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

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)

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