Dolutegravir use and incidence of prediabetes and type 2 diabetes mellitus (209368)

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Study Finalised

Administrative details

EU PAS number

EUPAS26602

Study ID

42170

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: 08/04/2018

Actual: 08/04/2018

Study start date
Planned: 14/12/2018

Actual: 03/12/2018

Data analysis start date
Actual: 01/05/2019

Date of final study report
Planned: 07/10/2019

Actual: 07/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-209368-protocol-redact.pdf(1.76 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 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 assess the baseline prevalence of and the incidence rate over follow-up of prediabetes and T2DM among new users of DTG, RAL, EVG/c and DRV (/r/c), and to estimate the association between core agent initiation (DTG vs. to RAL, EVG/c or DRV(/r/c)) and development of T2DM

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

A total of four distinct study populations were identified from the OPERA Observational Database for analysis per the inclusion criteria defined below:

Population 1 (Primary objective 1)

Inclusions:

1) A diagnosis of HIV, a positive HIV Western Blot, or a positive HIV enzymelinked immunosorbent assay (ELISA); and a detectable HIV viral load test.

2) At least 13 years of age at the index date.

3) Male, female, or transgender

4) Never diagnosed with type 1 or juvenile DM

5) Initiating DTG, RAL, EVG/c or DRV(/r/c) for the first time between 01AUG2013 and 31MAR2018

6) Not Exposed to >1 core agent of interest concurrently

7) Viral load measured within 120 days prior to baseline

Population 2 (Primary objectives 2 & 3, Secondary objective 1, exploratory objectives 1 & 2)

Inclusions:

1) A diagnosis of HIV, a positive HIV Western Blot, or a positive HIV enzymelinked immunosorbent assay (ELISA); and a detectable HIV viral load

test.

2) At least 13 years of age at the index date.

3) Male, female, or transgender

4) Never diagnosed with type 1 or juvenile DM

5) Initiating DTG, RAL, EVG/c or DRV(/r/c) for the first time between 01AUG2013 and 31MAR2018

6) Not Exposed to >1 core agent of interest concurrently

7) Viral load measured within 120 days prior to baseline

8) No diagnosis of T2DM at or before core agent initiation

Population 3 (Secondary objective 2)

Inclusions:

1) A diagnosis of HIV, a positive HIV Western Blot, or a positive HIV enzymelinked immunosorbent assay (ELISA); and a detectable HIV viral load test.

2) At least 13 years of age at the index date.

3) Male, female, or transgender

4) Never diagnosed with type 1 or juvenile DM

5) Initiating DTG, RAL, EVG/c or DRV(/r/c) for the first time between 01AUG2013 and 31MAR2018

6) Not Exposed to >1 core agent of interest concurrently

7) Viral load measured within 120 days prior to baseline

8) Diagnosis of T2DM at or before core agent initiation

Population 4 (Secondary objective 3)

Inclusions:

1) A diagnosis of HIV, a positive

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

15000

Study design details

Data analysis plan

Descriptive analyses will be conducted for patients prescribed a core agent of interest between 01AUG2013 and 31MAR2018. Pairwise comparisons between DTG and each of the other core agent groups will be evaluated by p-values calculated from Pearson Chi-Square test for categorical variables. Fisher's exact test will be used to compare frequencies with few events. Wilcoxon Rank Sum test will be used to calculate p-values for continuous variables. All descriptive analyses will be stratified by ART-naïve, ART-experienced, suppressed, and ART-experienced, not suppressed.

Documents

Study results

viiv-209368-clinical-study-report-redact.pdf(3.64 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