A multi-site observational study to assess safety and effectiveness of prenatal exposure to Dolutegravir in pregnant individuals living with HIV (212976)

First published: 13/11/2019

Last updated: 25/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS32268

Study ID

42405

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

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/06/2019

Actual: 28/06/2019

Study start date

Planned: 30/04/2020

Actual: 15/04/2020

Date of final study report
Planned: 31/10/2023

Actual: 18/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-212976-protocol-redact.pdf (856.13 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 type:

Non-interventional study

Scope of the study:

Other

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

Retrospective chart review

Main study objective:

To describe the demographic and clinical characteristics of pregnant women exposed to DTG, to assess the frequency of birth defects among neonates with prenatal exposure to DTG (categorized by timing of earliest exposure), to describe non-defect pregnancy and neonatal outcomes of the DTG exposed pregnancies, and to assess virologic outcomes among pregnant women on DTG based treatment regimen.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Medicinal product name

TIVICAY

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

DOLUTEGRAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AX12) dolutegravir

dolutegravir

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

2.000

Study design details

Outcomes

Pregnancy outcomes including spontaneous abortion, induced abortion, still births/live births, preterm births, low birth weight and prevalence of birth defects, maternal VL at delivery (<50 copies/mL & ≥200 copies/mL) and neonatal HIV status.

Data analysis plan

Analyses will be conducted to assess if there are any associations between DTG exposure and outcomes for pregnancy and birth. Logistic regression and Cox proportional-hazards models will be used. Potential confounding factors will be included in a step-wise approach to determine whether they change the odds ratio (OR) or the hazard ratio (HR) for DTG exposure at significance level of 10% in the models. Significant factors modifying the risk of DTG exposure will be retained. Final models will be adjusted on the selected confounders.

Documents

Study report

Clinical Study Report Anonymised 05 Apr 2024.pdf (1.89 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)

Other

Data sources (types), other

Retrospective chart review

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