Prenatal Exposure to Dolutegravir and Pregnancy and Neonatal Outcomes: Data from Antiretroviral Pregnancy Registry (206242)

First published: 21/06/2016

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Study Ongoing

Administrative details

EU PAS number

EUPAS13840

Study ID

47350

DARWIN EU® study

No

Study countries

Argentina

Australia

Belgium

Botswana
Brazil
Canada
China
Dominican Republic
Ethiopia
France
Germany
Haiti
Israel
Kenya
Nigeria
Portugal
Puerto Rico
Russian Federation
South Africa
Spain
Switzerland
Thailand
Uganda
United Kingdom
United States
Zimbabwe

Study description

Descriptive analysis of prospectively collected data from the APR on prenatal exposure to dolutegravir

Study status

Ongoing

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: 13/06/2016

Actual: 13/06/2016

Study start date

Planned: 12/08/2016

Actual: 11/08/2016

Date of interim report, if expected

Planned: 01/06/2017

Actual: 09/10/2017

Date of final study report

Planned: 31/03/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

gsk-206242-protocol-redact.pdf (174.75 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

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

Descriptive analysis

Data collection methods:

Primary data collection

Study design:

Descriptive analysis of prospectively collected data

Main study objective:

1. To describe the demographic and clinical characteristics of pregnant women exposed to dolutegravir (DTG) (Tivicay & Triumeq)
2. To assess the frequency of birth defects among neonates, with prenatal exposure to DTG (Tivicay & Triumeq)
3. To describe non-defect pregnancy outcomes among live birth

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive analysis

Study drug and medical condition

Medicinal product name

TIVICAY

TRIUMEQ

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

ABACAVIR

DOLUTEGRAVIR

LAMIVUDINE

Anatomical Therapeutic Chemical (ATC) code

(J05AR13) lamivudine, abacavir and dolutegravir

lamivudine, abacavir and dolutegravir

(J05AJ03) dolutegravir

dolutegravir

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

All pregnant women exposed to DTG (Tivicay & Triumeq) and prospectively reported to the APR, from the cumulative APR data through January 2016.

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

1

Study design details

Comparators

Birth defect prevalence (any pregnancy outcome > 20 weeks of gestation with a defect/live births) is compared to both internal and external comparator groups. The external comparators used are two population-based surveillance systems – Metropolitan Atlanta Congenital Defects Program (MACDP) by Centers for Disease Control and Prevention (CDC) and the Texas Birth Defects Registry (TBDR); and internal comparators include exposures to other drugs and exposures in the 2nd or 3rd trimester of pregnancy relative to

1st trimester exposures when organogenesis occurs.

Outcomes

Outcomes of interest are live births, still births, induced abortion, spontaneous abortion, birth defects, low birth weight (LBW), very low birth weight (VLBW) and preterm births.

Data analysis plan

Demographic and clinical characteristics of the pregnant women will be tabulated. Frequency assessment of birth defects will be done among all live births.

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 source(s), other

Antiretroviral Pregnancy Registry (APR), United States

Data sources (types)

Drug registry

Other

Pregnancy registry

Data sources (types), other

Prospective patient-based data collection, Prospective pregnancy registry

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