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

First published: 21/06/2016

Last updated: 09/08/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS13840

Study ID

47350

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Australia
- ☐ Brazil

- [ ] Canada
- [ ] Ethiopia
- [ ] Israel
- [ ] Puerto Rico
- [ ] Russian Federation
- [ ] United Kingdom
- [ ] United States

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

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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: 01/07/2016

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 type list

Study type:

Non-interventional study

Scope of the study:

Other

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

Descriptive analysis

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

Name of medicine

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

(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

1

Study design details

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

Data sources

Data source(s), other

Antiretroviral Pregnancy Registry (APR), United States

Data sources (types)

Other

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