Pregnancy and Neonatal Outcomes following Prenatal Exposure to Dolutegravir: Data from the European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) (206254)

First published: 23/11/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16321

Study ID

48253

DARWIN EU® study

No

Study countries

☐ Argentina

☐ Ireland

- [ ] Italy
- [ ] Spain
- [ ] Switzerland
- [ ] Thailand
- [ ] United Kingdom

Study description

Descriptive analysis of prospectively collected data from EPPICC on prenatal exposure to dolutegravir (DTG)

Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

First published: 01/02/2024

Last updated: 01/02/2024

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: 04/11/2016

Actual: 04/11/2016

Study start date

Planned: 30/11/2016

Actual: 28/11/2016

Data analysis start date

Planned: 30/11/2016

Actual: 28/11/2016

Date of final study report

Planned: 30/06/2017

Actual: 11/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-206254-protocol-redact.pdf(175.88 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 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

Descriptive analysis

Data collection methods:

Primary data collection

Main study objective:

To describe patterns of prenatal use of DTG-containing regimens, maternal characteristics of women taking DTG-based regimens, frequency of adverse pregnancy outcomes in women using DTG in pregnancy, the proportion of women on DTG who achieve viral suppression by the end of pregnancy, and mother-to-child transmission (MTCT) rates in mother-infant pairs with prenatal DTG use.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective analysis

Study drug and medical condition

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

DOLUTEGRAVIR

ABACAVIR

LAMIVUDINE

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

Pregnant women living with HIV with any exposure to dolutegravir (TIVICAY® & TRIUMEQ®) at any time during the pregnancy and their infants identified from the EPPICC cohort (European Pregnancy and Paediatric HIV Cohort Collaboration) by the end of August 2016.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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

Other

Pregnant women

Special population of interest, other

Patients with HIV transmission

Estimated number of subjects

65

Study design details

Outcomes

Pregnancy outcomes (live births, still births, induced abortion, spontaneous abortion, birth defects, low birth weight, very low birth weight and preterm births), maternal viral suppression at end of pregnancy, and infant’s HIV infection status

Data analysis plan

Descriptive statistics will be used to summarize demographic/clinical characteristics and outcomes of interest

Documents

Study results

viiv-206254-clinical-study-report-redact.pdf(1.96 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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