DOLOMITE EPPICC Study: Pregnancy and Neonatal Outcomes following Prenatal Exposure to Dolutegravir: Data from the European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) (208613)

First published: 07/03/2018

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS22915

Study ID

42167

DARWIN EU® study

No

Study countries

- [ ] Italy
- [ ] Romania

- [ ] Russian Federation
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

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 GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/11/2017

Actual: 20/11/2017

Study start date
Planned: 23/03/2018

Actual: 08/03/2018

Date of final study report
Planned: 31/07/2023

Actual: 19/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-208613-protocol-redact.pdf(598.86 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

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

Observational cohort analysis

Data collection methods:

Primary data collection

Main study objective:

To describe trends and patterns of use of dolutegravir (DTG)-containing regimens in pregnancy in Europe, to describe frequency of adverse pregnancy outcomes in women using DTG in pregnancy, to describe the proportion of women on DTG who achieve viral suppression by the end of pregnancy, and to describe 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

Observational analysis

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

The study population included all pregnant women living with HIV exposed to any DTG (TIVICAY®, TRIUMEQ®, JULUCA and D3) at any time during the pregnancy and their infants identified from the EPPICC network.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

150

Study design details

Outcomes

Pregnancy outcomes including spontaneous abortion, induced abortion, live birth, and still birth by trimester of exposure to DTG, adverse pregnancy outcomes including birth defects, preterm and severely preterm births, low birth weight, very low birth weight, and extremely low birth weight infants, maternal virological suppression at the end of pregnancy and MTCT rates.

Data analysis plan

Statistical analysis will be carried out using STATA® v12.0 software (StataCorp, College Station, Texas). Standard descriptive statistics will be used to summarize the data. For continuous variables, the sample size, median and interquartile range will be provided. Frequency distributions will be provided for categorical variables. For rates, 95% confidence intervals will be calculated.

Documents

Study results

Study Report DOLOMITE EPPIC_Pregnancy_Final Report Anonymized 03 Nov 2023.pdf(1.87 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