Pregnancy and Neonatal Outcomes following Prenatal Exposure to Cabotegravir Long Acting (CAB LA): Data from the European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) (215163)

First published: 16/02/2022

Last updated: 05/06/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47336

EU PAS number

EUPAS45777

Study ID

47336

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Poland
- [ ] Romania
- [ ] Russian Federation
- [ ] Spain
- [ ] Switzerland
- [ ] Ukraine
- [ ] United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor

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: 09/11/2020

Actual: 09/11/2020

Study start date

Planned: 01/03/2022

Actual: 18/02/2022

Date of final study report

Planned: 30/06/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-215163-protocol-orig-redact.pdf(1.03 MB)

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 type:

Non-interventional study

Main study objective:

1. Describe maternal characteristics by timing of 1st CAB exposure in relation to estimated date of conception;

2. Est. frequency of adverse pregnancy and neonatal outcomes, by timing of 1st CAB exposure;

3. Est. perinatal transmission rates in mother-infant pairs;

4. Assess proportion of women who achieve viral suppression by the end of pregnancy, by trimester of exposure.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational clinical cohort analysis

Study drug and medical condition

Name of medicine

VOCABRIA

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

CABOTEGRAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AX) Other antivirals

Other antivirals

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

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

Pregnant women

Estimated number of subjects

0

Study design details

Outcomes

• Demographic, clinical and immunological characteristics, co-infections, timing of CAB LA initiation, other ARVs used in the regimen;

• No. with adverse pregnancy outcome, infants with adverse neonatal outcome, with perinatal transmission rates in mother-infant pairs, percentage achieving viral suppression.

Data analysis plan

Frequency distributions for categorical variables and summary measures for continuous variables will be used for descriptive analyses. For rates, 95% confidence intervals will be calculated. The unit of analysis will vary depending on outcome and multiple gestations will be taken into account where appropriate. Descriptive analyses will include the whole study population.

Analyses for preterm and low birth weights will be restricted to live singleton births, birth defects will be estimated among live births, maternal viral suppression estimates will be restricted to women delivering live or stillborn infants, and vertical transmission analyses will be limited to live-born infants. There will be four analyses: the first analyses when the number of pregnant women exposed to CAB containing regimen in the cohorts reaches 25, followed by two more analyses when the study pop reaches 100 and 200 pregnancies. A final analysis will be done 12 months after the 3rd analysis.

Data management

Data sources

Data source(s), other

European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC)

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