Pregnancy and Neonatal Outcomes following Prenatal Exposure to Cabotegravir: Data from The Antiretroviral Pregnancy Registry (APR) (215325)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47339

EU PAS number

EUPAS45685

Study ID

47339

DARWIN EU® study

No

Study countries

☐ Czechia

☐ France

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: 29/10/2020

Actual: 29/10/2020

Study start date
Planned: 17/03/2022

Actual: 18/02/2022

Date of final study report
Planned: 30/12/2029

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Other
- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-215325-protocol-orig-redact.pdf(1.02 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:

• To describe maternal characteristics by timing of first exposure to CAB.

• To estimate frequency of birth defects among neonates, w/prenatal exposure to CAB, by timing of first exposure.

• To estimate frequency of non-defect adverse pregnancy and neonatal outcomes, by timing of first 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
• Number of participants with live births, induced or spontaneous abortion, or stillbirth
• Number of neonates with low/very low/extremely low birth weight
• Number of infants with preterm birth or severe preterm birth
• Incidence of birth defects

Data analysis plan

Four analyses will be conducted: the first analyses when the number of pregnant women exposed to CAB containing regimen during first trimester in the cohort reaches 25, followed by two more analyses when the study population reaches 100 and 200 pregnancies with first trimester exposures to CAB. A final analysis will be done 12 months after the 3rd analysis. This analysis will be descriptive in nature. Demographic and clinical characteristics of the pregnant women will be tabulated. Frequency assessment of birth defects will be done among all live births. Only singleton births will be included in the analysis of non-defect outcomes, multiple births such as twin and triplet births will be excluded due to the increased risk of adverse outcomes associated with

such pregnancies.

Data management

Data sources

Data source(s), other

Antiretroviral Pregnancy Registry (APR)

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Exposure 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