Observational Pregnancy Surveillance Program of Patients Exposed to Epidiolex®/Epidyolex® During Pregnancy to Assess the Risk of Pregnancy and Maternal Complications and Other Events of Interest on the Developing Fetus, Neonate, and Infant

First published: 21/11/2023

Last updated: 18/10/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107706

EU PAS number

EUPAS107705

Study ID

107706

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Latvia
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia

- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study status

Planned

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

- [ ] Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Vicki Osborne

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/05/2023

Study start date

Planned: 30/11/2023

Date of final study report

Planned: 30/11/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GW Pharmaceuticals, part of Jazz pharmaceuticals

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Main study objective:

Pregnancy outcomes and pregnancy complications in patients who were exposed to at least 1 dose of Epidiolex during the 13 days prior to their LMP or during pregnancy The prevalence of MCM identified in fetuses, neonates, and infants, and the prevalence of other events of interest identified in neonates and infants through 12 months of age who were exposed to at least 1 dose of Epidiolex in utero

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX24) cannabidiol

cannabidiol

Population studied

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)

Estimated number of subjects

50

Study design details

Data analysis plan

Data regarding MCM will be presented as proportions (percent of total outcomes) and prevalence rates and 95% confidence interval (CI) will be presented. Data will be presented for the proportion of the total number of pregnancies that result in spontaneous abortion, elective or therapeutic abortion, fetal death/stillbirth, or preterm delivery, and for infants who are small for gestational age. The proportion of pregnancies that result in live births of infants that experience complications, such as delays in growth and development milestones, and hospitalizations during the first 12 months of life for infants at 3, 6, 9, and 12 months of age ± 2 weeks, will be calculated.

Data management

Data sources

Data sources (types)

Other

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