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: 21/11/2023

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 institution and networks

Institutions

United BioSource Corporation (UBC)

Switzerland
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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:
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

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