Pregistry International Pregnancy Exposure Registry (PIPER)

First published: 20/04/2022

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS46841

Study ID

48094

DARWIN EU® study

No

Study countries

- Canada
- Nigeria
- Philippines
- South Africa
- United Kingdom
- United States

Study description

The aims of the Pregistry International Pregnancy Exposure Registry (PIPER) are to provide early signals of risk after prenatal exposure to medical products and to define boundaries of safety for medical products. The goal is to assist prescribers and study participants in weighing the potential risks of prenatal treatments on the wellbeing of mother and the unborn offspring. Specifically, the PIPER will estimate the risk of obstetric outcomes (spontaneous abortion, antenatal bleeding, gestational diabetes, gestational hypertension, intrauterine growth restriction, postpartum hemorrhage, fetal distress, uterine rupture, placenta previa, chorioamnionitis, Caesarean delivery, COVID-19), neonatal outcomes (major congenital malformations, low birth weight, neonatal death, neonatal encephalopathy, neonatal infections, neonatal acute kidney injury, preterm birth, respiratory distress in the newborn, small for gestational age, stillbirth, COVID-19), and infant outcomes (developmental milestones motor, cognitive, language, social-emotional, and mental health skills, height, weight, failure to thrive, medical conditions during the first 12 months of life, COVID-19) among pregnant women.

Study status

Planned

Research institutions and networks

Institutions

Pregistry

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Institution

Contact details

Study institution contact

Wyszynski Diego hello@pregistry.com

Study contact

hello@pregistry.com

Primary lead investigator

Wyszynski Diego

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/12/2021

Study start date

Planned: 16/07/2022

Data analysis start date

Planned: 15/07/2032

Date of final study report

Planned: 15/07/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pregistry, LLC

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Main study objective:

The aims of the Pregistry International Pregnancy Exposure Registry (PIPER) are to provide early signals of risk after prenatal exposure to medical products and to define boundaries of safety for medical products. The goal is to assist prescribers and study participants in weighing the potential risks of prenatal treatments on the wellbeing of mother and the unborn offspring.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Pregnancy registry

Study drug and medical condition

Medical condition to be studied

Pregnancy

Drug exposure before pregnancy

Stillbirth

Abortion spontaneous

Gestational hypertension

COVID-19

Population studied

Age groups

- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

10000

Study design details

Outcomes

Risk of obstetric, neonatal, and infant outcomes.

Data analysis plan

There are no a priori defined primary or secondary endpoints in the PIPER. The aim is to conduct surveillance of adverse events (AEs) potentially associated with prescription medical products in the United States. As described below, the analyses will include a descriptive component, a real-time disproportional reporting evaluation, a clinical assessment of similar cases, and analyses of causal inference.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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