COVID-19 International Drug Pregnancy Registry (COVID-PR)

First published: 23/08/2021

Last updated: 20/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS42517

Study ID

49846

DARWIN EU® study

No

Study countries

- Australia
- Canada
- Denmark
- Germany
- Italy
- Japan

Singapore

United Kingdom

United States

Study description

The objective of the COVID-19 International Drug Pregnancy Registry (COVID-PR) is to evaluate obstetric, neonatal, and infant outcomes among women treated with monoclonal antibodies or antiviral drugs indicated for mild, moderate, or severe COVID-19 from the first day of the last menstrual period (LMP) to end of pregnancy.

For monoclonal antibodies, the exposure period also includes 90 days prior to the first day of the LMP.

The study outcomes are risk of obstetric outcomes (spontaneous abortion, intrauterine growth restriction, gestational diabetes, gestational hypertension, postpartum hemorrhage, Caesarean delivery), neonatal outcomes (major congenital malformations, low birth weight, small for gestational age, neonatal infections, stillbirth, neonatal death, preterm birth), and infant outcomes until 12 months of age (developmental milestones motor, cognitive, language, social-emotional, and mental health skills, height, weight, failure to thrive).

Study status

Ongoing

Research institutions and networks

Institutions

Pregistry

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Institution

Contact details

Study institution contact

Cheryl Renz covid-pr@pregistry.com

Study contact

covid-pr@pregistry.com

Primary lead investigator

Cheryl Renz

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/06/2021

Study start date

Planned: 03/01/2022

Actual: 01/10/2021

Date of final study report

Planned: 31/08/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline, Gilead, Roche, Merck Sharp & Dohme

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

ClinicalTrials.gov Identifier: NCT05013632

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Other

Study topic, other:

COVID-19 International Drug Pregnancy Registry

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Main study objective:

The objective of the COVID-19 International Drug Pregnancy Registry (COVID-PR) is to evaluate obstetric, neonatal, and infant outcomes among women treated with monoclonal antibodies or antiviral drugs indicated for mild, moderate, or severe COVID-19 from the first day of the LMP to end of pregnancy.
For monoclonal antibodies, the exposure period also includes 90 days prior to the first day of LMP.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VEKLURY

XEVUDY

Medicinal product name, other

REGEN-COV, Lagevrio

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

REMDESIVIR

SOTROVIMAB

Anatomical Therapeutic Chemical (ATC) code

(J06BD05) sotrovimab

sotrovimab

(J05AB16) remdesivir

remdesivir

Medical condition to be studied

SARS-CoV-2 test positive

Population studied

Age groups

- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1000

Study design details

Outcomes

Risk of obstetric outcomes (spontaneous abortion, intrauterine growth restriction, gestational diabetes, gestational hypertension, postpartum hemorrhage, Caesarean delivery), neonatal outcomes (major congenital malformations, low birth weight, small for gestational age, neonatal infections, stillbirth, neonatal death, preterm birth), and infant outcomes until 12 months of age.

Data analysis plan

The reference groups will provide an estimate of the expected incidence of obstetric, neonatal, and infant outcomes in women from a similar source population and risk factors as the exposed cohort.
The exposed and reference cohorts will be matched by calendar time, country of residence, gestational week at the time of COVID-19 infection (± 2 weeks), and severity of COVID-19.

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 source(s)

Other data source

Data source(s), other

Prospective patient-based data collection, Exposure registry

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