Registry for pregnant women exposed to SARS-CoV-2 (COVID-19, CONSIGN study) (COVI-PREG)

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Study Finalised

Administrative details

EU PAS number

EUPAS39226

Study ID

40543

DARWIN EU® study

No

Study countries

- Argentina
- Belgium
- Brazil
- Chile

- Colombia
- Egypt
- France
- French Guiana
- Germany
- Ireland
- Israel
- Italy
- Mexico
- Peru
- Portugal
- Spain
- Switzerland
- United Kingdom
- United States

Study description

The COVI-PREG registry aims to collect data to understand the natural history of the SARS-CoV-2 among pregnant women and the impact on maternal, pregnancy and neonatal outcomes. The COVI-PREG project is part of the Covid-19 infectiOn aNd medicineS In preGNancy (CONSIGN) project that study the impact of COVID-19 infection and medicines in pregnancy, as work package 3. The mains objectives are to describe, among positive SARS-CoV-2 pregnant women, the use of medicines, the impact of medicine use on COVID-19 severity and on pregnancy and neonatal outcome.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 150 centres are involved in the study

Contact details

Study institution contact

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Study contact

alice.panchaud@chuv.ch

Primary lead investigator

Alice Panchaud

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/03/2020

Study start date

Actual: 24/03/2020

Date of final study report

Planned: 31/07/2023

Actual: 27/10/2022

Sources of funding

- EMA
- Other

More details on funding

Swiss Public health office, CHUV, UNIBe

Study protocol

COVIDPREG_register_protocol_ExternalPartnairs.pdf (356.82 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

Trial registration number: ID 2020-00548 – Swissethics (Swiss Association of Research Ethics Committee)

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

i.To characterise the clinical course of SARS-CoV-2 infection during pregnancy ii.To assess the risk assessment of vertical transmission and congenital lesions iii.To quantify the risk of adverse maternal outcomes, pregnancy outcomes and neonatal outcomes iv. To identify additional risk factors and risk modifiers

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

The study population comprised of pregnant women with suspected SARS-CoV-2 infection from April 2020 to April 2024.
Inclusion criteria: Pregnant women with a suspicion of infection by SARS-CoV-2
Exclusion criteria: Patients considered as minor in their jurisdiction and patients who have not given their informed consent or are not able to consent for themselves will not be considerate eligible in the registry.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

3000

Study design details

Outcomes

maternal, obstetrical and neonatal outcomes

Data analysis plan

It will be evaluated for each future research question by the Registry Scientific Advisory Committee and a biomedical research Ethics committee. Interim analysis to get an early appraisal of study findings might be considered for

some aims and will be submitted for approval to a biomedical research Ethics committee.

Documents

Study publications

Favre G, Gerbier E, Maisonneuve E, Pomar L, Winterfeld U, Lepigeon K, Bloemenka…

Favre Guillaume, Bromley Rebecca, Maisonneuve Emeline, & Panchaud Alice. (2023)…

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

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