International Registry of Coronavirus Exposure in Pregnancy (IRCEP)

First published: 25/09/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37360

Study ID

46740

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] Brazil
- [ ] Canada

- [ ] Chile
- [ ] Colombia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Ghana
- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Japan
- [ ] Kenya
- [ ] Mexico
- [ ] Netherlands
- [ ] New Zealand
- [ ] Nigeria
- [ ] Pakistan
- [ ] Portugal
- [ ] Russian Federation
- [ ] South Africa
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

The International Registry of Coronavirus Exposure in Pregnancy (IRCEP) aims to describe the natural history of COVID-19 in pregnant women and to estimate the relative risk of major adverse obstetric and neonatal outcomes among women with varying degrees of severity and of timing of COVID-19 exposure

and their offspring, respectively.

Study status

Finalised

Research institutions and networks

Institutions

Pregistry

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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Contact details

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Primary lead investigator

Diego Wyszynski

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/02/2020

Study start date
Actual: 01/07/2020

Date of final study report
Actual: 01/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson & Johnson, Regeneron

Study protocol

IRCEP_Protocol_17Apr2020.pdf (664.15 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

https://corona.pregistry.com,ClinicalTrials.gov Identifier: NCT04366986

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

The International Registry of Coronavirus Exposure in Pregnancy (IRCEP) aims to describe the natural history of COVID-19 in pregnant women and to estimate the relative risk of major adverse obstetric and neonatal outcomes among women with varying degrees of severity and of timing of COVID-19 exposure and their offspring, respectively.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pregnancy

SARS-CoV-2 test positive

Exposure during pregnancy

Stillbirth

Abortion spontaneous

Congenital anomaly

Foetal malformation

Pre-eclampsia

Foetal growth restriction

Population studied

Short description of the study population

The target study population consists of pregnant women, 18 years of age or older, tested for SARS-CoV-2 or with clinical confirmation of COVID-19, willing to provide information using the IRCEP website or mobile app. The rationale for including cases without a positive test is that in the worst-hit areas, where nucleic acid tests were scarce, epidemiological considerations and clinical symptoms (i.e., pneumonia, chest CT findings) sufficed to assign a diagnosis.
Inclusion criteria
1. Pregnant women or women that delivered or had a pregnancy loss within the last 180 days
2. Aged 18 years or older
3. Tested for SARS-CoV-2 or had clinical confirmation of COVID-19 between the last menstrual period (LMP) and delivery
4. Able and willing to sign the informed consent form agreeing to the conditions and requirements of the IRCEP, and
5. Willing to upload the minimum required data of the initial baseline questionnaire

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Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

18000

Study design details

Outcomes

Multiple maternal, obstetric, neonatal, and infant outcomes.

Data analysis plan

There are two main data analyses: 1) a real-time descriptive surveillance that will report the COVID-19 characteristics and the frequency of outcomes in the exposed and control groups, and 2) hypothesis-based causal inference analyses that will investigate the potential effects of specific COVID-19 characteristics or treatments and will adjust through multivariate regression models or using propensity score (PS) matching to account for potential confounders, as appropriate.

Documents

Study, other information

Correspondence_for_IRB20-0622 6-8-2020.pdf (120.67 KB)

Sonia Hernandez-Diaz Correspondence_for_MOD20-0622-01.pdf (111.36 KB)

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