COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER)

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Study Ongoing

Administrative details

EU PAS number

EUPAS39096

Study ID

46745

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Croatia
- [ ] Cyprus

- [ ] Denmark
- [ ] Germany
- [ ] Greece
- [ ] Hong Kong
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Malaysia
- [ ] Mexico
- [ ] New Zealand
- [ ] Nigeria
- [ ] Philippines
- [ ] Romania
- [ ] Singapore
- [ ] Slovakia
- [ ] Slovenia
- [ ] South Africa
- [ ] United Kingdom
- [ ] United States

Study description

The objective of the COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER) is to evaluate obstetric, neonatal, and infant outcomes among women vaccinated during pregnancy with a COVID-19 vaccine. Specifically, the C-VIPER 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 exposed to single (homologous) or mixed (heterologous) COVID-19 vaccine brand series from 30 days prior to the first day of the last menstrual period to end of pregnancy and their offspring relative to a matched reference group who received no COVID-19 vaccines during pregnancy.

Study status

Ongoing

Research institutions and networks

Institutions

Pregistry

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Institution

Contact details

Study institution contact

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Study contact

c-viper@pregistry.com

Primary lead investigator

Diego Wyszynski

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/01/2021

Study start date

Planned: 01/06/2021

Actual: 17/05/2021

Date of final study report

Planned: 30/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, Janssen, Novavax, Sanofi

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: NCT04705116

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

Main study objective:

The objective of the COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER) is to evaluate obstetric, neonatal, and infant outcomes among women vaccinated during pregnancy with a COVID-19 vaccine.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

COVID-19 immunisation

Population studied

Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

3000

Study design details

Outcomes

Multiple obstetric, neonatal, and infant outcomes.

Data analysis plan

To assess the effect of each COVID-19 vaccine brand on pregnancy outcomes, the risk of pregnancy outcomes among women exposed to a COVID-19 vaccine (from Cohort 1) at specific times during pregnancy will be compared to a reference group of women who have not received a COVID-19 vaccine during

pregnancy up to that point, matched 1:2 on country of residence and gestational age at enrollment (±2 weeks).

Documents

Study, other information

InitialReviewNotice_37742718.pdf(30.46 KB)

IRB_Approval_11March2022.pdf(87.49 KB)

Data management

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