Safety and effectiveness of COVID-19 maternal immunisation: An update of available evidence

First published: 14/06/2022

Last updated: 03/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS47697

Study ID

47698

DARWIN EU® study

No

Study countries

- Brazil
- Canada
- Israel
- Norway

Qatar
Romania
Sweden
United Kingdom
United States

Study description

There are still relatively limited data on the safety and effectiveness of COVID-19 vaccines during pregnancy. Even scarcer are data on how vaccination during pregnancy or lactation protects the infant during the first months of life. We presented an updated overview of the evidence on COVID-19 maternal immunisation including studies published between January 1, 2021, through June 7, 2022. We identified 29 studies, of which 21 reported results on vaccine safety and 12 reported results on vaccine effectiveness (VE) during pregnancy. None of the studies reported on the potential protective effect of maternal immunisation during lactation of breastfed infants. Findings from included studies suggest that mRNA COVID-19 vaccines are not associated with an increased risk of adverse outcomes in pregnant women and their neonates and are effective in reducing the incidence of SARS-CoV-2 infection in both mothers and infants. The low incidence of maternal COVID-19-related hospitalisation and severe disease precluded the studies from providing precise VE estimates for these outcomes. Despite the number of published studies, there remain major gaps in our knowledge of how COVID-19 vaccines impact pregnancy and newborns. Strong evidence is needed based on large population-based studies that use rigorous methods and include diverse populations that could confirm these initial findings. Evidence is still scarce on ideal timing of immunisation and number of doses to provide protection to the pregnant women and their infants, vaccine safety during the first trimester of pregnancy, vaccine effectiveness of boosters and against emerging SARS-CoV-2 variants as well as evidence on safety and effectiveness of viral vector vaccines or inactivated

vaccines. Additionally, whether COVID-19 vaccine-derived antibodies transferred from the mothers to their infants during breastfeeding provide protection against SARS-CoV-2 infection or health complications remains to be elucidated.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Maria Clara Restrepo-Mendez
mariaclara.restrepomendez@ext.ema.europa.eu

Study contact

mariaclara.restrepomendez@ext.ema.europa.eu

Primary lead investigator

Maria Clara Restrepo-Mendez

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 21/03/2022

Actual: 21/03/2022

Study start date
Planned: 11/04/2022

Actual: 11/04/2022

Date of final study report
Planned: 13/06/2022

Actual: 13/06/2022

Sources of funding

- EMA

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective of this scoping literature review was to identify and compile the most recent evidence on the safety and effectiveness of COVID-19 vaccination during pregnancy and breastfeeding.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medical condition to be studied

Abortion spontaneous

Postpartum haemorrhage

Stillbirth

Small for dates baby

COVID-19

Additional medical condition(s)

Caesarean delivery, Pregnancy related hypertensive disorders, Preterm birth, Neonatal Intensive Care Unit (NICU) admission, Congenital anomalies, Low birth weight, Neonatal hospitalisation, COVID-19-related hospitalization, COVID-19-related severe illness

Population studied

Short description of the study population

The study focused on effect of covid-19 vaccines on pregnant women and their neonates identified from the Embase and PubMed databases between January 1, 2021, to June 7, 2022.

Age groups

- Preterm 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

290.000

Study design details

Outcomes

Pregnancy and delivery outcomes Neonatal outcomes Vaccine effectiveness against SARS-CoV-2 infection COVID-19-related hospitalisation and severe illness

---

Data analysis plan

A literature search was conducted to include studies published between January 1, 2021, through June 7, 2022. The information sources were EMBASE and PubMed database. The search key terms included: pregnancy, maternal, fetal, birth, perinatal, neonatal, newborn, infant, breastfeeding, lactation AND covid-19 vaccine, covid-19 vaccination, SARS-CoV-2 vaccine. Studies were included if they presented a comparison group (e.g. unvaccinated women) or used background rates, and if they addressed at least one of the following topics: (1) Safety of COVID-19 vaccines during pregnancy with pregnancy, delivery, or neonatal outcomes, or (2) effectiveness of COVID-19 vaccines against SARS-CoV-2 infection, severe COVID-19 illness, or COVID-19-related complications or death, in pregnant women or their infants. Additionally, we included studies looking at the potential protective effect of COVID-19 vaccination during breastfeeding of infants.

Documents

Study results

Report_COVID-19 maternal immunisation review_20220610.pdf (471.89 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

Scoping literature review using EMBASE and PubMed databases.

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