Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries (COVID-19)

First published: 29/11/2021

Last updated: 11/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS44450

Study ID

45467

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Italy
- ☐ Norway

☐ Spain

☐ United Kingdom

Study description

The overarching research question is: is there a greater risk or prevalence of pregnancy complications, adverse pregnancy outcomes, or adverse neonatal outcomes following pregnancies exposed to Spikevax compared with pregnancies unexposed to Spikevax?

Study status

Finalised

Research institutions and networks

Institutions

Aarhus University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aarhus University Hospital

Julius Clinical Research

☐ Netherlands

First published: 02/03/2021

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

☐ Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

University of Oslo

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Oslo Norway, Julius Clinical The Netherlands

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

☐ Belgium

☐ Denmark

☐ Finland

☐ France

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

Last updated: 22/09/2020

Network | Outdated | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/03/2021

Study start date
Planned: 31/12/2021

Actual: 31/12/2021

Date of final study report
Planned: 30/03/2024

Actual: 23/01/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Moderna

Study protocol

mRNA-1273-P905_EU_PASS_Pregnancy_Protocol_1.2 27Sep2021 redacted for ENCePP.pdf (2.03 MB)

mRNA-1273-P905_EU_PASS_Pregnancy_Protocol_sv1.2_27SEP22.pdf (865.26 KB)

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)

Methodological aspects

Study topic:

Human medicinal product

Study topic, other:

Vaccine

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

8.1. Primary objectives:

To determine whether exposure to the Spikevax during pregnancy is associated with an increased risk of:

a. Pregnancy complications

b. Adverse pregnancy outcomes

c. Major congenital malformations in the offspring (overall and organ-specific if feasible)

d. Adverse neonatal outcomes

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medicinal product name

SPIKEVAX

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

300000

Study design details

Outcomes

a. Pregnancy complications

b. Adverse pregnancy outcomes

c. Major congenital malformations in the offspring (overall and organ-specific if feasible)

d. Adverse neonatal outcomes, Utilization of Spikevax in pregnancy

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Data analysis plan

Counts and percentages will be presented for categorical variables (age at conception in categories, sex). Means, standard errors, medians and ranges will be presented for continuous variables (age at conception).

The proportion of missing data will be described when appropriate.

For maternal outcomes, pregnancy will be the unit of observation, for neonatal outcomes, a newborn will be the unit of observation. For the outcomes of congenital malformations and stillbirth the number at risk will be the total number of live or stillborn children.

Prevalence of each outcome will be computed as number of observations with a given outcome divided by the total number of study population members.

For neonatal death, a 28-day mortality risk will be the measure of occurrence among live-born infants.

Prevalence/risks will be compared according to predefined exposure categories and using, whenever necessary, plausible exposure risk windows.

Documents

Study report

mRNA-1273-P905_FinalCSV_fv1.0 (Final Study Report).pdf (706.92 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 source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

ARS Toscana

Data source(s), other

NorPD

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Exposure registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

ConcepTION CDM

CDM website

https://www.imi-conception.eu/

CDM release frequency

6 months

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after extract-transform-load to a common data model