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: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45467

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

Ongoing

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: 23/02/2024

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 **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: 31/12/2023

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)

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 type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

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

Name of medicine

SPIKEVAX

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

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.

Data management

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)

Drug dispensing/prescription data

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