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

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## Administrative details

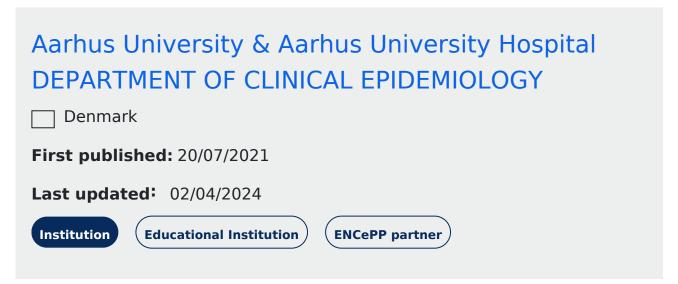
EU PAS number	
EUPAS44450	
Chudu ID	
Study ID	
45467	
DARWIN EU® study	
No	
Study countries	
Denmark	
Italy	
Norway	

☐ 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



# 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

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Institution Educational Institution Laboratory/Research/Testing facility
Not-for-profit ENCePP partner
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Institution
University of Oslo Norway, Julius Clinical The
Netherlands
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Vaccine monitoring Collaboration for Europe
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Belgium
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## Contact details

## **Study institution 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

# 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

#### **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	
<b>Check stability</b> Yes	
Check logical consistency Yes	
Data characterisation	
<b>Data characterisation conducted</b> Yes	

### **Data characterisation moment**

after extract-transform-load to a common data model