Observational Study to Assess Pregnancy and Infant Outcomes Following Exposure to Updated Moderna Vaccines Targeting SARS CoV-2 During Pregnancy

First published: 26/09/2025

Last updated: 26/09/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000750

Study ID

1000000750

DARWIN EU® study

No

Study countries

United States

Study description

The aim of this study is to assess whether receipt of updated Spikevax formulations (mRNA-1273.222 or mRNA-1273.815) during pregnancy is associated with an increased rate of pregnancy complications, adverse pregnancy outcomes, or adverse infant outcomes.
The secondary objectives of this study are to assess whether exposure to Spikevax during pregnancy is associated with a change in rate of infant hospitalization due to COVID-19 in the first 6 months of life and to describe Spikevax utilization during pregnancy.

Study status

Ongoing

Research institutions and networks

Institutions

Optum Insight Life Sciences

Networks

Optum Insight Life Sciences

Contact details

Study institution contact

Clinical Trial Disclosure ModernaTX cttd@modernatx.com

Study contact

cttd@modernatx.com

Primary lead investigator

Clinical Trial Disclosure ModernaTX

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/07/2024

Study start date
Actual: 15/07/2024

Data analysis start date
Actual: 06/12/2024

Date of final study report
Planned: 15/05/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ModernaTX

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

mRNA-1273-P949

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

No individual level data collected for the purpose of the study

Study design:

Retrospective cohort study design

Main study objective:

1: To assess whether exposure to Spikevax during pregnancy is associated with an increased rate of the following pregnancy complications:

a. Gestational hypertensive disorders;

b. Gestational hypertension;

c. Pre-eclampsia;

d. Eclampsia o Gestational diabetes.

2: To assess whether exposure to Spikevax during pregnancy is associated with an increased rate of the following pregnancy outcomes: a. Medically-attended spontaneous abortion; b. Stillbirth; c. Preterm birth.

3. To assess whether exposure to Spikevax during pregnancy is associated with an increased prevalence of infant major congenital malformation (MCM)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SPIKEVAX

Medicinal product name, other

mRNA-1273.222 or mRNA-1273.815

Population studied

Short description of the study population

Pregnancies among women aged 12-50 years

Special population of interest

Pregnant women

Study design details

Data analysis plan

This study will be conducted using a sequential cohort design that aligns cohort entry at gestational week of vaccination. Spikevax-exposed pregnancies will be matched in a 1:4 ratio to unexposed pregnancies based on gestational week, age, calendar time at cohort entry, and propensity score. We will estimate prevalence ratios using robust Poisson regression models and hazard ratios using Cox proportional hazards models.

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)

Non-interventional study

Other

Data sources (types), other

Optum Research Database

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes