mRNA-1273-P919: An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to SPIKEVAX During Pregnancy

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000058

Study ID

1000000058

DARWIN EU® study

No

Study countries

☐ United States

Study description

This observational post-marketing safety study is designed to evaluate the risk of adverse pregnancy outcomes, birth outcomes, infant outcomes, or early life infections following maternal exposure to Spikevax during pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Carelon Research

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: 02/11/2022

Study start date
Actual: 28/10/2023

Data analysis start date
Actual: 01/03/2023

Date of final study report
Actual: 29/03/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Moderna TX, Inc.

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)

Other study registration identification numbers and links

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

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Study design:

This is a claims-based retrospective cohort study comparing adverse pregnancy and neonatal outcomes among pregnant women exposed to Spikevax with three reference populations.

Main study objective:

This study aims to assess whether there is an increased risk of pregnancy complications, adverse pregnancy outcomes, or adverse neonatal outcomes in pregnancies exposed to Spikevax compared with pregnancies unexposed to

Spikevax.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SPIKEVAX

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

ELASOMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

Population studied

Short description of the study population

The source population for this study consists of women of childbearing age in the HealthCare Integrated Research Database (HIRD) with pharmacy and medical benefits, from 01 December 2019 to 01 January 2023.

Special population of interest

Pregnant women

Study design details

Setting

The source population for this study includes women of childbearing age in the HIRD from 01 December 2019 to 01 Jan 2023. It will include the following groups:

(a) pregnant women exposed to Spikevax (primary exposure) from last menstrual period (LMP) through the exposure ascertainment period of the outcome of interest.

(b) pregnant women not exposed to Spikevax or any other COVID-19 vaccine at any time within 60 days prior to LMP or from LMP through the exposure ascertainment period of the outcome of interest.

(c) pregnant women who were exposed to Spikevax at least 60 days prior to the LMP but not from the LMP to exposure ascertainment period of the outcome of interest.

(d) Pregnant women not exposed to Spikevax or any other COVID-19 vaccine within 60 days prior to LMP with medically attended COVID-19 infection at least once from LMP through the exposure ascertainment period of the outcome of interest.

Outcomes

Outcomes of interest in infants include prevalence of major congenital malformations (MCMs), neonatal encephalopathy, small-for-gestational-age, respiratory distress in the newborn, and hospitalization due to infections (including COVID-19).

Outcomes in pregnant women include prevalence of hypertensive disorders (including preeclampsia, eclampsia, and gestational hypertension), gestational diabetes, post-partum hemorrhage, stillbirth, preterm birth, and medically attended spontaneous abortion.

Data analysis plan

Descriptive analyses will characterize pregnant women in the exposed and comparator groups regarding their demographics and health-related characteristics. The frequency of the outcomes of interest for pregnant women exposed to Spikevax will also be described.

Comparative analyses will be performed separately for each outcome and contrast of interest, estimating birth prevalence ratios for outcomes measured as birth prevalence (e.g., MCM), prevalence ratios for outcomes measured as a prevalence (e.g., preeclampsia), or hazard ratios for outcomes measured based on incidence (e.g., infant hospitalizations in the first year of life) both unadjusted and adjusted for confounding via propensity score weighting.

Data management

Data sources

Data source(s), other

HealthCare Integrated Research Database (HIRD)

American Community Survey (ACS)

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Yes

Data characterisation details

Data validation is planned to occur throughout the data management and analysis process. Data quality checks include, but are not limited to, programming checks by an individual who is not the main programmer for the study, internal dataset consistency, and checks to ensure that Protocol criteria were met.