Moderna mRNA-1273 Observational Pregnancy Outcome Study (COVID-19)

First published: 11/06/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48937

EU PAS number

EUPAS41463

Study ID

48937

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] United States

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

David Martin

Study contact

David.martin@modernatx.com

Primary lead investigator

Eleonora Staines Urias

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/05/2021

Study start date
Planned: 22/07/2021

Actual: 01/09/2021

Date of final study report
Planned: 06/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Moderna

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 list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

The Moderna COVID-19 Vaccine Pregnancy Registry will collect primary data from pregnant women who have received the Moderna COVID-19 vaccine and their healthcare providers

Main study objective:

The main goal of this study is to evaluate the outcomes of pregnancy in females exposed to the Moderna COVID-19 vaccine (mRNA-1273) during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ELASOMERAN

IMELASOMERAN

Medical condition to be studied

Multiple congenital abnormalities

Additional medical condition(s)

Preeclampsia, eclampsia, pregnancy-induced hypertension, antenatal bleeding, preterm labor, gestational diabetes, dysfunctional labor, premature rupture of membranes, placenta previa, postpartum hemorrhage, small–for–gestational-age (SGA) fetus and intrauterine growth restriction, and non-reassuring fetal status. Spontaneous abortions, fetal death or stillbirth and COVID-19 diagnosis.

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

1000

Study design details

Outcomes

1. Number of Participants Having Infants With Suspected Major and Minor Congenital Malformations. 2. Number of Participants With Any Pregnancy Complications 3. Number of Participants With Any Pregnancy Outcomes 4. Number of Participants With Infant Outcomes

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Data analysis plan

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied. Continuous variables will be reported as mean (and standard deviation) or median and range where appropriate. Categorical variables will be summarized as number and proportion of the total study population, and by subgroups where appropriate. The study will evaluate the proportion of major congenital malformations in infants of women exposed to the Moderna COVID-19 vaccine at any point from 28 days prior to LMP through pregnancy as well other maternal, fetal, and infant outcomes variables identified for the subgroup analysis will be evaluated as potential confounders in the comparative analysis of the risk ratio for major congenital malformations in the Moderna COVID-19 vaccine exposed and external comparator (when possible).

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Exposure registry, Case-control surveillance database

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