Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47692

EU PAS number

EUPAS42869

Study ID

47692

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] United States

Study description

This study aims to answer the question "Is the risk of pregnancy and infant safety outcomes increased among pregnant women in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry ("OTIS Pregnancy Registry") who were vaccinated with the Pfizer-BioNTech COVID-19 vaccine during pregnancy compared with those who did not receive any COVID-19 vaccine during pregnancy?" The study objective is to assess whether pregnant women who received the Pfizer-BioNTech COVID-19 vaccine during pregnancy experienced increased risk of pregnancy and infant safety outcomes, including major congenital malformations, spontaneous abortion, elective termination/abortion, stillbirth, preterm delivery, small for gestational age, and small for age postnatal growth at one year of age, relative to pregnant women who received no COVID-19 vaccines during pregnancy. This study is a prospective, observational cohort study of pregnancy and infant safety outcomes in pregnant women with exposure to the Pfizer-BioNTech COVID-19 vaccine using data from the OTIS Pregnancy Registry. The birth prevalence, incidence rates, and incidence proportion of pregnancy outcomes and incidence proportion of the infant outcome for women exposed to any dose of the Pfizer-BioNTech COVID-19 within one month prior to the first day of the last menstrual period to end of pregnancy will be compared to those observed in a comparator cohort unexposed to any COVID-19 vaccine during this period.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of California

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jenny Sun

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/05/2021

Actual: 06/05/2021

Study start date
Planned: 01/10/2021

Actual: 01/10/2021

Date of final study report
Planned: 28/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

Study protocol

C4591022_PROTOCOL AMENDMENT 1_20AUG2021.pdf(3.37 MB)

C4591022_PROTOCOL AMENDMENT 3_V4_09MAY2022.pdf(3.39 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 list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To assess whether pregnant women who received the Pfizer-BioNTech COVID-19 vaccine during pregnancy experienced increased risk of pregnancy and infant safety outcomes relative to pregnant women who received no COVID-19 vaccines during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BX03) covid-19 vaccines

covid-19 vaccines

Medical condition to be studied

COVID-19 immunisation

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

2000

Study design details

Outcomes

Pregnancy outcomes of interest include major congenital malformations, spontaneous abortion, elective termination/abortion for any reason, stillbirth, preterm delivery, and small for gestational age. The infant outcome of interest is small for age postnatal growth of live born infants at one year of age.

Data analysis plan

The distributions of demographic and baseline characteristics will be summarized within the exposure and comparator cohort. The following measures will be calculated for the pregnancy and infant outcomes: birth prevalence of major congenital malformations, incidence rates of spontaneous abortion, elective termination/abortion, stillbirth, and preterm delivery, and incidence proportions of small for gestational age and small for age postnatal growth at one year of age. For each outcome, risk estimates will be described separately for the Pfizer-BioNTech COVID-19 vaccine exposure cohort and the comparator cohort. The outcomes will be compared between the Pfizer-BioNTech COVID-19 vaccine-exposed and vaccine-unexposed cohorts. Where feasible, comparisons will also be made using methods to control potential confounding and to evaluate outcomes following receipt of specific doses (i.e. 1st, 2nd, 3rd, booster) in pregnancy.

Data management

Data sources

Data sources (types)

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