A Non-Interventional Post-Approval Safety Study of Pfizer-BioNTech COVID-19 Vaccine in the United States

First published: 19/10/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS43468

Study ID

48132

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study will use a retrospective cohort design of individuals with concurrent unexposed comparators. The study will compare the incidence of safety events among individuals who have received a first, second, or third dose in a primary series of Pfizer-BioNTech COVID-19 Vaccine with that among individuals who have no record of any COVID-19 vaccine in a concurrent time period. Additionally, in individuals aged 5 years and older who have received 2 doses in a primary series of Pfizer-BioNTech COVID-19 Vaccine, the incidence of safety events among individuals who have received a third dose (either as an additional dose in a primary series or as an initial booster dose) of the vaccine more than 2 months after the second dose will be compared with that among individuals who have not received a third dose of any COVID-19 vaccine. Finally, the study will compare the prevalence of birth outcomes (including major congenital malformations and small size for gestational age) in infants born to pregnant women who have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine during an exposure window of interest with that among infants born to pregnant women who have not received any COVID-19 vaccine during the exposure window of interest. The source population for this study will be health plan enrollees from 5 data research partners that contribute data from claims and electronic health records to the Sentinel System: CVS Health/Aetna, HealthCore/Anthem, HealthPartners, Humana, and Optum. Safety events of interest will be identified in claims and electronic health records (where available) using predefined algorithms based on diagnosis codes, with procedure and/or pharmacy dispensing codes as appropriate.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Harvard Pilgrim Health Care Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nana Koram

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/11/2020

Actual: 05/11/2020

Study start date
Planned: 30/06/2022

Actual: 17/06/2022

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591009_PROTOCOL_19AUG2021 (1).pdf(3.62 MB)

C4591009_PROTOCOL AMENDMENT 3_V4_30JUN2023.pdf(2.16 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

Drug utilisation

Main study objective:

To estimate the relative risk of safety events of interest (including myocarditis/pericarditis) following receipt of a first, second, or third dose in a primary series of Pfizer-BioNTech COVID-19 Vaccine compared with no receipt of any COVID-19 vaccine within the overall study population and subgroups of pregnant women, immunocompromised individuals, and individuals with a history of COVID-19.

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

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

Immunocompromised

Pregnant women

Estimated number of subjects

1

Study design details

Outcomes

Adverse events of special interest as listed in the protocol, Among the overall study population and subgroups of interest: the proportion of individuals receiving the Pfizer-BioNTech COVID-19 vaccine, stratified by number of doses, timing and type of second/third doses, demographics and comorbidities.

Data analysis plan

Descriptive analysis will report on utilization of Pfizer-BioNTech COVID-19 Vaccine during the overall study period and in sequential increments of time. Characteristics of the matched and unmatched cohorts will be shown in a table. Vaccinated individuals will be matched to concurrent unexposed comparators. Confounding will be addressed through propensity score matching or through the inclusion of propensity scores in exposure-outcome regression models. In each data source, crude measures of incidence or prevalence of the study outcomes with associated 95% confidence intervals (CIs) will be estimated within the matched exposed and unexposed cohorts. Cox models or Poisson regression will be used to estimate risk ratios and 95% CIs for general safety events in the overall population and subgroups of interest. Sensitivity analyses will incorporate a self-controlled risk interval design or a cohort design with historical comparators in a period before the introduction of COVID-19 vaccines.

Documents

Study, other information

C4591009_PROTOCOL AMENDMENT 2_V3_07JUL2022.pdf(4.63 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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