Post-Emergency Use Authorization Active Safety Surveillance Study among Individuals in the Veteran’s Affairs Health System Receiving Pfizer BioNTech Coronavirus Disease 2019 (COVID 19) Vaccine

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Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS39779

Study ID

103367

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to answer the research question what are the incidence rates of safety events of interest (based on adverse events of special interest) among individuals vaccinated with the Pfizer-BioNTech COVID 19 vaccine within the US Veterans Health Administration (VHA) system overall and in sub-cohorts of interest, as compared to expected rates of those events? The primary study objectives are: 1) to assess whether the following groups of individuals in the VHA system experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 vaccine: individuals receiving first dose, individuals receiving the primary series of two doses, individuals receiving additional approved dose(s) of the Pfizer-BioNTech COVID-19 vaccine after the primary series of two doses and 2) to assess whether sub-cohorts of interest (i.e. immunocompromised, elderly, individuals with specific comorbidities, individuals receiving only one dose of the Pfizer-BioNTech COVID-19 vaccine, individuals with prior SARS-CoV-2 infection, individuals with regular use of VHA medical care, VA priority group 1 Veterans, and individuals with dual coverage of VHA and Medicare) in the VHA system experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 vaccine. This post-EUA active safety surveillance program will employ a rapid-cycle, longitudinal, observational cohort study design to provide early real-world safety information. The self-controlled risk interval design will be used to sequentially monitor occurrence of safety events of interest while controlling for time-invariant confounders. An active comparator design will be used to sequentially monitor occurrence of safety events of interest with Pfizer-BioNTech COVID-19 vaccinations as compared to recipients of influenza vaccine in the VHA. Additional study designs will be conducted if a signal is detected from these analyses.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Analysis Group, Inc., U.S. Department of Veterans Affairs

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kofi Asomaning

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/11/2020

Actual: 13/11/2020

Study start date
Planned: 01/05/2021

Actual: 11/03/2021

Date of final study report
Planned: 31/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591012 VHA Protocol_1.27.2021_Final 27 JAN 2021.pdf (1.12 MB)

C4591012_PROTOCOL AMENDMENT 5_V6_31JAN2023.pdf (2.9 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

Disease epidemiology

Drug utilisation

Main study objective:

To assess whether the following groups of individuals in the VHA system experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 vaccine: individuals receiving first dose, individuals receiving the primary series of two doses, individuals receiving additional approved doses of the Pfizer-BioNTech COVID-19 vaccine after the primary series of two doses

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

- 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

Estimated number of subjects

107458

Study design details

Outcomes

Risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 vaccine among various groups of individuals and sub-cohorts of interest in the VHA system, The proportion of individuals receiving at least one dose of the the Pfizer-BioNTech COVID-19 vaccine, 2-dose vaccine completion rate, additional approved dose(s) completion rate, distribution of time gaps between the first and second dose and between the second and additional approved dose(s), and demographics and health histories of recipients, overall and among the subcohorts of interest

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Data analysis plan

A stepwise approach will be performed for signal detection, evaluation, and verification. Signal detection: The maximized sequential probability ratio test (MaxSPRT) using a binomial probability model will be applied to the self-controlled risk interval (SCRI) analysis and the Poisson-based MaxSPRT to the comparison group. Signals will be detected if the critical values are reached via the SCRI or active comparator analysis. Signal evaluation: Detected signals will be confirmed through quality assurance and multivariate adjustment using Poisson regression to account for differences between vaccinated and active comparator cohorts. SCRI and self-controlled case series analyses will be conducted as well as a comparison to contemporary unvaccinated controls. Signal verification: Diagnostic validation of the detected safety events of interest via adjudication of medical records by VHA clinicians for outcome verification will be conducted in a representative sample of cases.

Documents

Study results

C4591012_ABSTRACT AND FINAL REPORT FOR EU PAS_08DEC2023.pdf (2.69 MB)

Data management

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 source(s), other

Veterans Health Administration Corporate Data Warehouse United States

Data sources (types)

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