Active Safety Surveillance of the Pfizer-BioNTech COVID-19 Vaccine in the United States Department of Defense Population Following Emergency Use Authorization

First published: 03/07/2023

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS50375

Study ID

107862

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 AESI), overall and in sub-cohorts of interest, among individuals in the United States DoD Military Health System (MHS) vaccinated with the Pfizer-BioNTech COVID-19 Vaccine as compared to expected rates of those events? The primary objectives are 1) to assess whether individuals identified in the DoD MHS experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 Vaccine, specifically in the following groups: individuals receiving at least one dose, individuals receiving the primary series, and individuals receiving approved booster dose(s) of the Pfizer-BioNTech COVID-19 Vaccine after the primary series and 2) to assess whether sub-cohorts of interest (ie, pregnant women, immunocompromised, elderly, individuals with specific comorbidities, individuals receiving only one dose of the Pfizer-BioNTech COVID-19 Vaccine, and individuals with prior SARS-CoV-2 infection) identified in the DoD MHS experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 Vaccine. This post-EUA active safety surveillance study will employ a retrospective, longitudinal, observational cohort study design. The observed safety event of interest rates in the cohort of individuals who received the Pfizer-BioNTech Vaccine between 11 December 2020 and 30 June 2023 will be compared to expected rates derived in 3 control groups: active comparator cohort, general population comparator cohort, and self-controls. Update: Study C4591011 was terminated in 14 September 2023, the study objectives were addressed by earlier availability of data from multiple other studies with similar study endpoints and analyses. No study reports were prepared.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Analysis Group, Inc., The Henry M. Jackson Foundation for the Advancement of Military Medicine Inc., Defense Health Agency

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Heather Ward

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/01/2021

Actual: 28/01/2021

Study start date
Planned: 31/01/2023

Actual: 14/09/2023

Date of final study report
Planned: 31/01/2025

Actual: 14/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591011_PROTOCOL AMENDMENT 2_09AUG2022.pdf (3.41 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Main study objective:

To assess whether individuals identified in the DoD MHS experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 Vaccine, specifically in the following groups: individuals receiving at least 1 dose, individuals receiving the primary series, individuals receiving approved booster dose(s) of the Pfizer-BioNTech COVID-19 Vaccine after the primary series

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BX03) covid-19 vaccines

covid-19 vaccines

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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)

Estimated number of subjects

1

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 DoD MHS, The proportion of individuals receiving at least 1 dose of the vaccine, 2-dose and 3-dose vaccine completion rates, booster dose(s) completion rate, distribution of time gaps between doses for the primary series

and between completion of the primary series and booster dose(s), demographics and health histories of recipients, overall and among the sub-cohorts of interest

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Data analysis plan

The cohort design will compare the incidence of the safety event of interest between a COVID-19 vaccine recipient cohort and the respective comparator cohorts as follows: Multivariate adjustment using Poisson regression will be conducted for the selected safety events of interest, comparing incidence rates of safety events in individuals receiving COVID-19 vaccine to active comparators. Risk of safety events among COVID-19 vaccinated individuals and contemporary unvaccinated controls will be compared using inverse probability of treatment weighting. SCCS design with a post-vaccination control time period will be conducted for the selected safety events of interest. Case validation/adjudication through medical records review may be conducted if a statistically significant finding of association is found. Descriptive statistics will be used to summarize baseline demographics, clinical characteristics, and vaccine utilization patterns. Various subgroup analyses will also be conducted

Data management

ENCePP Seal

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

United States Department of Defense Military Health System United States

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