HERO-Together: A post-Emergency Use Authorization observational cohort study to evaluate the safety of the Pfizer-BioNTech COVID-19 vaccine in US healthcare workers, their families, and their communities

First published: 17/12/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38671

Study ID

46811

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study is a prospective observational study designed to evaluate the incidence rates of safety events of interest and other clinically significant events within a cohort of healthcare workers, their families, and their communities who receive the Pfizer-BioNTech COVID-19 vaccine under the EUA program in the United States. The study is a primary data collection study with review of medical records. Receipt of the vaccine is required for inclusion in the study, but the decision to be vaccinated is made at the discretion of the recipient. This study will aim to enroll and follow 20,000 vaccinated healthcare workers and members of their families or communities during a 30-month study period. Information on hospitalization and diagnosis of safety events of interest will be collected from participant self-report at regular intervals following vaccination, primarily using a secure web portal. Participant reports of safety events of interest and/or hospitalization trigger a request for and review of participant medical record information for adjudication of the event. To address the primary objective, incidence rates of safety events will be estimated based on cases confirmed by adjudication. To address the secondary objective regarding assessment of increased risk, a self-matched comparative analysis will be undertaken for feasible safety events (e.g. events with a known risk interval and sufficient case counts). Additional context for the rates observed in vaccinated individuals will be sought from population background rates.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Duke Clinical Research Institute (DCRI)

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Last updated: 01/02/2024

Institution

Verily Life Sciences, CVS Health Clinical Trial Services

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katie Kendrick

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 14/12/2020

Actual: 14/12/2020

Study start date
Planned: 17/12/2020

Actual: 17/12/2020

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

Actual: 07/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591008 v1 16Dec2020 Non-Interventional Post Authorization Safety Study (PASS) Protocol.pdf(1.26 MB)

C4591008_PROTOCOL AMENDMENT 3_17AUG2023.pdf(648.39 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

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:

Estimate the real-world incidence of safety events of interest and other clinically significant events among US healthcare workers, their families, and their communities who are vaccinated with the Pfizer-BioNTech COVID-19 vaccine following Emergency Use Authorization.

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

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

20000

Study design details

Outcomes

Incidence of safety events of interest and other clinically significant events among US healthcare workers, their families, and their communities who are

vaccinated with the Pfizer-BioNTech COVID-19 vaccine following Emergency Use Authorization, Increased risk of safety events of interest and other clinically significant events post vaccination, incidence rates of safety events of interest and other clinically significant events among subcohorts of interest such as individuals who are pregnant, individuals who are immunocompromised, and stratified by age

Data analysis plan

Vaccination and baseline characteristics will be summarized using descriptive statistics, including measures of central tendency and dispersion (means, medians, standard deviations) for continuous variables and percentages for categorical variables. The primary analysis for each objective will be restricted to participants who enrolled within 10 days of vaccination to mitigate the risk of selective enrollment and disproportionate representation of higher risk participants. The number and incidence rate for each safety event of interest will be calculated overall, and within subgroups of interest, including pregnant women, immunocompromised individuals, and within age groups. Rates will also be stratified by other baseline characteristics, such as race/ethnicity, work setting and geographic region, data permitting. To evaluate whether vaccinated persons experience increased risk, we will use qualitative and quantitative comparison approaches.

Documents

Study results

C4591008_ABSTRACT AND FINAL REPORT FOR EU PAS_30NOV2023.pdf(6.3 MB)

Study, other information

C4591008_PROTOCOL AMENDMENT 2_20APR2021.pdf(3.17 MB)

Data management

Data sources

Data source(s), other

Healthcare Worker Exposure Response and Outcomes (HERO) Registry United States, Project Baseline by Verily United States, CVS Pharmacy COVID-19 vaccine registration platform United States

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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