

Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

First published: 22/08/2022

Last updated: 20/02/2024

Study

Planned

Administrative details

Contact details

Study institution contact

Cynthia de Luise

Study contact

cynthia.deluise@pfizer.com

Primary lead investigator

Cynthia de Luise

Primary lead investigator

PURI

<https://redirect.ema.europa.eu/resource/47709>

EU PAS number

EUPAS47708

Study ID

47709

Study countries

Italy

Netherlands

Norway

Spain

United Kingdom

Study description

This study will address the following research question, "What is the clinical course of myocarditis and pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries?" This cohort study is nested in the ongoing retrospective cohort study (EUPAS41623) titled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine." The parent study includes individuals across 5 European countries who receive at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine, as well as individuals who did not receive a COVID-19 vaccine. For the primary objective (natural history), the study will be conducted in the cohort of cases of myocarditis and of pericarditis identified in the full population of the parent study. For the secondary objective (risk factors), the study will be conducted using the population from the parent study component in which vaccinated and unvaccinated individuals are matched 1:1 on date of vaccination in the vaccinated group and date of study eligibility in the unvaccinated group. Individuals are also matched on age, sex, history of COVID-19, place of residence, history of influenza vaccination, pregnancy status, immunocompromised status, presence of pre-existing medical conditions, and socioeconomic status/education level. The matching variables, vaccination status, and other baseline variables to be identified in a review of the medical literature will be considered as potential risk factors for the development of myocarditis and of pericarditis.

Study status

Planned

Research institution and networks

Institutions

Pfizer**First published:** 01/02/2024

Last updated 01/02/2024

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated

22/02/2024

Institution

Hospital/Clinic/Other health care facility

Educational Institution

ENCePP partner

Fondazione Penta ONLUS

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

Belgium

Denmark

Finland

France

Germany

Italy

Netherlands

Norway

Spain

United Kingdom

First published: 22/09/2020

Last updated

22/09/2020

Network

ENCePP partner

Study timelines

Date when funding contract was signed

Planned:

27/10/2021

Actual:

27/10/2021

Data collection

Planned:

31/12/2022

Date of final study report

Planned:

30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

[C4591038_PROTOCOL AMENDMENT 2_V3_13MAY2022.pdf](#)(4.52 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:

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To describe the clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis or pericarditis among individuals diagnosed with myocarditis and/or pericarditis after receiving at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals diagnosed

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

200000015711

covid-19 vaccines

Medical condition to be studied

Myocarditis

Additional medical condition(s)

Pericarditis

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)

Estimated number of subjects

1

Study design details

Outcomes

Potential outcomes for myocarditis are treatment, recovery, survival, hospitalisations, sudden cardiac death, heart failure, cardiogenic shock, fulminant myocarditis, inflammatory cardiomyopathy, heart transplant, and arrhythmia. Potential outcomes for pericarditis are treatment, recovery, survival, hospitalisations, and chronic, restrictive, and recurrent pericarditis. Potential risk factors for myocarditis and pericarditis, such as age, sex, Pfizer-BioNTech COVID-19 vaccination status, vaccine doses received (e.g. first, second, third, and booster doses), and history of COVID-19

Data analysis plan

For the primary objective, the distributions of vaccination status and other baseline characteristics will be described. For continuous variables, means, standard deviations and quartiles will be estimated. For categorical variables, counts and proportions will be estimated. The missingness of variables will also be described. The occurrence of the different treatments and outcomes during follow-up will be described using counts and proportions. Continuous variables (e.g. length of stay) will be described using means, standard deviations and quartiles. When appropriate, the occurrence of time-to-event outcomes (e.g. death) will be described using the Kaplan-Meier estimator or curve. Analysis will be performed overall by sex and age, COVID-19 history, vaccination status, and time since vaccination.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink
The Information System for Research in Primary Care
PHARMO Data Network
ARS Toscana
Pedianet network
EpiChron Cohort
Hospital Episode Statistics

Data source(s), other

Norwegian health registers Norway, HSD Italy

Data sources (types)

[Administrative data \(e.g. claims\)](#)

[Disease registry](#)

[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