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

PURI
https://redirect.ema.europa.eu/resource/47709

EU PAS number
EUPAS47708

Study ID
47709

DARWIN EU® study
No

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
Institution

University Medical Center Utrecht (UMCU)
Netherlands
First published: 24/11/2021
Last updated 22/02/2024
Institution
Educational Institution
Hospital/Clinic/Other health care facility
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

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Cynthia de Luise
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
27/10/2021
Actual:
27/10/2021

Study start date
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:
Non-interventional study

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)
Adults (85 years and over)

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