Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

First published: 25/06/2021
Last updated: 20/06/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/46939

EU PAS number
EUPAS41623

Study ID
46939

DARWIN EU® study
No

Study countries
Italy
Netherlands
Norway
Spain
United Kingdom

Study description
A retrospective cohort design will be used to estimate the incidence of adverse events of special interest (AESI) after receiving the Pfizer-BioNTech COVID-19 vaccine doses and compare this incidence with that occurring in an unvaccinated comparator group matched

on relevant individual characteristics (eg, age, comorbidities). Where appropriate, the study will also use a self-controlled risk interval (SCRI) design. The source population will comprise all individuals registered in each of the healthcare data sources who are eligible to receive the Pfizer-BioNTech COVID-19 vaccine. The study period will start on the date of launch of the Pfizer-BioNTech COVID-19 vaccine and will end on the date of the latest data availability or 31 Dec 2023. It is expected that follow-up will last for 2 years for AESI. People who are pregnant at time of vaccination or who become pregnant within two years of study start and their live born infants will be followed for an additional 12 months to collect information about birth outcomes and linked infant outcomes. Exposure will be based on recorded prescription, dispensing, or administration of the Pfizer-BioNTech COVID-19 vaccine. Vaccine administration and date of vaccination should be obtained from all possible sources that capture COVID-19 vaccination. The outcomes will be based on the AESI proposed by the European Medicines Agency sponsored ACCESS project (vACcine COVID-19 monitoring readinESS). AESI will be identified based on patient profile review of electronic records by healthcare professionals. In addition, manual review of patient charts conducted by clinicians blinded to COVID-19 vaccine exposure will be performed. Confirmation of an event diagnosis will be classified against existing definitions of the Brighton Collaboration and those currently being developed. The study will be performed within select data sources from Netherlands, Italy, Spain, United Kingdom, and Norway.

Study status
Ongoing

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

RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
First published: 21/04/2010
Last updated 19/02/2024

Institution | ENCePP partner | Not-for-profit

Teamit Institute

Spain
First published: 12/03/2024
Last updated 12/03/2024

Institution | ENCePP partner | Other

Fundazione 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
Katie Kendrick
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
15/12/2020
Actual:
15/12/2020

Study start date
Planned:
30/09/2021
Actual:
03/09/2021

Date of final study report
Planned:
20/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591021_PROTOCOL_20MAY2021____.pdf(844.83 KB)

C4591021_PROTOCOL AMENDMENT 5_V7.0_15MAY2024.pdf(1.22 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

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology
Drug utilisation

Main study objective:
To determine whether an increased risk of prespecified AESI exists following the administration of at least one dose the Pfizer-BioNTech COVID 19 vaccine using two approaches: (a) a cohort design comparing risk in vaccinated and non-vaccinated individuals and (b) a self-controlled risk interval (SCRI) design.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Self-controlled case series

Study drug and medical condition

Name of medicine
COMIRNATY

Study drug International non-proprietary name (INN) or common name
COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)
FAMTOZINAMERAN
RAXTOZINAMERAN
RILTOZINAMERAN
TOZINAMERAN

Anatomical Therapeutic Chemical (ATC) code
(J07BN01) covid-19, RNA-based vaccine
(J07BX03) covid-19 vaccines

Medical condition to be studied
COVID-19 immunisation

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)

Special population of interest
Immunocompromised
Pregnant women

Estimated number of subjects
13225000

Study design details

Outcomes
Risk of prespecified AESI following the administration of at least one dose the Pfizer-BioNTech COVID-19 vaccine using two approaches: (a) a cohort design comparing risk in vaccinated and non-vaccinated individuals and (b) a self-controlled risk interval (SCRI) design, Incidence rates of prespecified AESI among individuals who receive at least one dose of the Pfizer-BioNTech COVID-19 vaccine using a cohort study design and compared with a matched comparator group with no COVID-19 vaccination within subcohorts of interest, including pregnant people and their neonates. Utilization patterns of Pfizer-BioNTech COVID-19 vaccine among individuals within Europe.

Data analysis plan
The distributions of baseline characteristics at time zero by exposure group will be calculated to describe the study cohort and illustrate differences between the groups. For safety outcomes, the risk over specific time period(s), incidence rates and their corresponding 95% confidence intervals (CIs) will be computed after the receipt of first, second, and subsequent doses. Crude risks, cumulative incidence over different time periods, and measures of association for each AESI after vaccination will be estimated in the entire population overall and separately by number of doses received. Subgroup analyses will be conducted by demographic and clinical characteristics as well as other covariates of interest. To account for potential confounding, propensity score methods will be used to estimate the adjusted risk ratios and 95% CIs. Appropriate random-effects meta-analytic methods will be used to obtain a combined effect estimate. Where appropriate, the study will also use a SCRI design.

Documents

Study report
C4591021_PROGRESS REPORT_27SEP2021.pdf(1.82 MB)
C4591021 NI Study Report Abstract - interim 1.pdf(1.29 MB)
c4591021-interim2-abstract.pdf(1.84 MB)
c4591021-interim3-abstract.pdf(659.37 KB)
c4591021-interim-abstract.pdf(703.59 KB)
C4591021 Interim 5 Study Report Abstract .pdf(120.38 KB)

Study, other information
C4591021_PROTOCOL AMENDMENT 2_31MAR2022.pdf(4.11 MB)

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink
The Information System for Research in Primary Care (SIDIAP)
PHARMO Data Network
ARS Toscana
Pedianet network
EpiChron Cohort
Norwegian Health Registers

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

CDM Mappings

CDM name
ConcepTION CDM

CDM website
https://www.imi-conception.eu/

CDM release frequency
6 months

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No