Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of Spikevax in Europe (COVID-19)

First published: 25/11/2021

Last updated: 23/02/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45470

EU PAS number

EUPAS44273

Study ID

45470

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

The overarching research question of this study: Is the occurrence of each adverse event of special interest (AESI) among persons vaccinated with Spikevax in Europe higher than the occurrence of that AESI that would have been expected in the same population in the absence of Spikevax? Primary objective: To assess whether vaccination with Spikevax (by dose number where feasible and for any dose) is associated with increased rates of the AESI compared with the expected rates overall and stratified by country, sex, and age group Secondary objective: To assess whether vaccination with Spikevax is associated with increased rates of the AESI compared with the expected rates in subpopulations of interest: women of childbearing age, patients who are immunocompromised, patients previously diagnosed with COVID-19 infection, patients with unstable health conditions and comorbidities, and patients with autoimmune or inflammatory disorders

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Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aarhus University Hospital

Julius Clinical Research

Netherlands

First published: 02/03/2021

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

University of Oslo

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Oslo Oslo, Norway, Julius Clinical Zeist, The Netherlands

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

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Network ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/05/2021

Actual: 26/05/2021

Study start date

Planned: 31/12/2021

Actual: 31/12/2021

Date of final study report

Planned: 31/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Moderna

Study protocol

mRNA-1273_P904_EU_PASS_Protocol_1.2. 27Sep2021 redacted for ENCePP.pdf (2.2 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

Main study objective:

Primary objective: -To assess whether vaccination with Spikevax (by dose number where feasible and for any dose) Secondary objective:- To assess whether vaccination with Spikevax is associated with increased rates of the AESI compared with the expected rates in subpopulations of interest

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

SPIKEVAX

Population studied

Age groups

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

500000

Study design details

Data analysis plan

Signal detection will be conducted first. For identified signals, signal evaluation will follow. For signal detection, the underlying analytic principle is the observed - expected (O-E) analysis, which aims to compare AESI rates in vaccinees, with the rates expected for a non-vaccinated population as similar as possible in its demographic and other relevant characteristics to the vaccinated population. For signal evaluation using self-controlled designs, the ratio between the incidence rate estimate in the risk period and the incidence rate estimate in the control period (incidence rate ratio) will be computed using conditional Poisson regression. For parallel cohort designs, appropriate contrasts will be estimated in exposed vs. unexposed cohorts, while controlling for measured confounding.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

ARS Toscana

Data source(s), other

Other linked Norwegian Registries Norway, NorPD

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Exposure registry, Routinely collected data on births, GP visits, hospital visits, vaccines, medicines, births, deaths, migrations.

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