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

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Study | Ongoing

Administrative details

Contact details

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Primary lead investigator

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

Study status
Ongoing

Research institution 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
Last updated 22/09/2020

Network ENCePP partner

Study timelines

Date when funding contract was signed
Planned:
26/05/2021
Actual:
26/05/2021

Data collection
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
ARS Toscana

Data source(s), other
Other linked Norwegian Registries Norway, NorPD

Data sources (types)
Administrative data (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