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 Finalised

Administrative details

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

Finalised

Research institutions and networks

Institutions

Aarhus University Hospital

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

Contact details

Study institution contact

Vera Ehrenstein ve@clin.au.dk

Study contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/05/2021

Study start date

Actual: 31/12/2021

Date of final study report

Actual: 10/03/2025

Sources of funding

More details on funding

Moderna

Study protocol

mRNA-1273_P904_EU_PASS_Protocol_sv1.4_clean_MOD.pdf (1.02 MB)

mRNA-1273_P904_EU_PASS_Protocol_sv1.3_27Sep2022_clean.pdf (1011.52 KB)

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

Medicinal product name

SPIKEVAX

Study drug International non-proprietary name (INN) or common name

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

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.

Documents

Study report

mRNA-1273-P904_FinalCSR_fv1.0_10March2025 compressed for HMA catalog.pdf (8.28 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

Norwegian Health Registers

Data source(s), other

Other linked Norwegian Registries Norway, NorPD

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Yes

CDM Mappings

CDM name

ConcepTION CDM

CDM website

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

CDM release frequency

6 months

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after extract-transform-load to a common data model