Effectiveness of monovalent XBB.1.5-containing Covid-19 mRNA vaccines in the Nordic countries

First published: 25/03/2024

Last updated: 10/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000043

Study ID

1000000043

DARWIN EU® study

No

Study countries

Denmark

Finland

Sweden

Study description

The aim of this project is to evaluate the comparative effectiveness of the monovalent XBB.1.5-containing Covid-19 vaccines in preventing severe Covid-19 outcomes among individuals aged 65 years or older. The study objectives include assessing vaccine effectiveness for preventing severe Covid-19 outcomes, evaluating waning effectiveness, and examining the impact of coadministration with influenza vaccines. We conduct nationwide register-based cohort analyses in Denmark, Finland, and Sweden from October 2023 to the latest available date in 2024. Source cohorts comprise known residents who received at least four Covid-19 vaccine doses between December 27, 2020, and the latest available date in 2024. Study cohorts include individuals aged 65+ eligible for an XBB.1.5-containing Covid-19 vaccine as a fifth or sixth dose. Outcomes of interest are Covid-19 hospitalization and death. Covariates include demographic factors, comorbidities, and previous Covid-19 vaccinations. We aim to include at least 3.1 million vaccine recipients across the three Nordic countries, utilizing all available data and ensuring statistical power reflected in 95% confidence intervals. Target trial emulation compares vaccinated individuals with controls in matched survival analyses, providing comparative effectiveness estimates while considering various covariates.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology Research, Statens Serum Institut

Denmark

First published: 16/03/2010

Last updated: 24/02/2012

Institution | Outdated | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner

Finnish Institute for Health and Welfare (THL)

Finland

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility

Data Analytic Center (DAC), Danish Medicine Agency

Denmark

First published: 17/04/2023

Last updated: 17/04/2023

Institution | EU Institution/Body/Agency | ENCePP partner

Swedish Medical Products Agency

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/01/2024

Actual: 08/01/2024

Study start date

Planned: 08/01/2024

Actual: 08/01/2024

Date of final study report

Planned: 19/04/2024

Actual: 07/06/2024

Sources of funding

- EMA

Study protocol

EMA_ROC17 Option_Study protocol .pdf (662.84 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The aim of this study is to evaluate the comparative effectiveness of the monovalent XBB.1.5-containing Covid-19 vaccines in preventing severe Covid-19 outcomes among individuals aged 65 years or older.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

COMIRNATY

SPIKEVAX

VAXZEVRIA

Medicinal product name, other

- Spikevax/Omicron XBB.1.5
- Comirnaty/Omicron XBB.1.5
- Comirnaty Original/Omicron BA.1 (BNT162b2)
- Comirnaty Original/Omicron BA.4-5 (BNT162b2)
- Comirnaty Original monovalent (BNT162b2)
- Spikevax Original/Omicron BA.1 (mRNA-1273 [/Moderna covid19 vaccine])
- Spikevax Original/Omicron BA.4-5 (mRNA-1273 [/Moderna covid19 vaccine])
- Spikevax Original monovalent (mRNA-1273 [/Moderna covid-19 vaccine])

- Vaxzevria (ChAdOx1-S [/AZD1222])

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

DAVESOMERAN

ELASOMERAN

FAMTOZINAMERAN

IMELASOMERAN

RAXTOZINAMERAN

RILTOZINAMERAN

TOZINAMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

(J07BN02) covid-19, viral vector, non-replicating

covid-19, viral vector, non-replicating

Medical condition to be studied

COVID-19

Population studied

Short description of the study population

Source cohorts will consist of all individuals who are known residents in the three Nordic countries and have received at least four Covid-19 vaccine doses between 27 December 2020 and latest available date in 2024. The study cohorts will consist of individuals who are at least 65 years of age in Denmark, Finland, and Sweden and eligible to receive an XBB.1.5-containing Covid-19

vaccine as a fifth or sixth dose during the study period.

Age groups

- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Estimated number of subjects

3.100.000

Study design details

Outcomes

The outcomes of interest are Covid-19 hospitalization and Covid-19 related death.

Data analysis plan

We will take advantage of the unique nationwide register-data available to us, and construct country cohorts with individual-level information on dates of vaccination and dates of effectiveness end-points together with relevant covariate information. Using target trial emulation, we will compare bivalent booster dose recipients head-to-head and with unboosted individuals in matched survival analysis that provides comparative effectiveness estimates while taking into account a range of covariates.

Documents

Study report

EMA ROC17 Option Study report.pdf (1.26 MB)

Data management

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), other

- The Civil Registration System (Denmark)
- The Danish Vaccination Register
- The Danish Microbiology Database
- The National Patient Register (Denmark)
- Finnish Population Information System
- Register of Social Assistance (Finland)
- Social and Healthcare Professionals Register (Finland)
- National Vaccination Register (Finland)
- National Infectious Diseases Register (Finland)
- National Care Register for Health Care (Finland)
- Special Reimbursement Register and Prescription Centre database (Finland)
- Register of Primary Health Care Visits (Finland)
- The Total Population Register (Sweden)
- The Cause of Death Register (Sweden)
- The Longitudinal Integrated Database For Health Insurance And Labour Market Studies (LISA) (Sweden)
- Register On Persons In Nursing Homes (Sweden)
- The National Vaccination Register (Sweden)
- Register On Surveillance Of Notifiable Communicable Diseases (Sminet) (Sweden)
- The Swedish Patient Register

Data sources (types)

Disease registry

Population registry

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