Effectiveness of bivalent Covid-19 booster vaccines in the Nordic countries

First published: 06/09/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS106558

Study ID

106559

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

Study description

The larger Nordic countries of Denmark, Finland, Norway, and Sweden, provide a unique setting for the study of Covid-19 vaccination effectiveness. The ubiquitous nationwide demography- and health registers, which includes SARS-CoV-2 immunization and surveillance registers, allows for very large study cohorts with near real-time data availability. Available evidence suggests that bivalent booster vaccinations during autumn 2022 provided additional protection against Covid-19 hospitalisations while protection against any SARS-CoV-2 infection is more modest. However, current studies only provide insight on effectiveness in follow-up periods that do not extend beyond 2-6 months and on the Omicron subvariants prevailing during the study period. The aim of this project is to evaluate the comparative effectiveness of the bivalent boosters in preventing severe Covid-19 outcomes and all-cause mortality among individuals aged 50 years or older with 1 year of follow-up.

Study status

Ongoing

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Institution | Outdated | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Anders Hviid

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2023

Actual: 01/08/2023

Study start date

Planned: 01/08/2023

Actual: 01/08/2023

Date of final study report

Planned: 08/01/2024

Sources of funding

- EMA

Study protocol

EMA_ROC17_STUDYPROTOCOL__ENCePP_v1_final_031023.pdf (1.22 MB)

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The aim of this project is to evaluate the comparative effectiveness of the bivalent boosters in preventing severe Covid-19 outcomes and all-cause mortality among individuals aged 50 years or older with 9 months of follow-up.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

- 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

Estimated number of subjects

3.400.000

Study design details

Outcomes

Covid-19 hospitalisation and Covid-19 mortality.

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, other information

ROC17_Study_Report_Encepp_Annex_final_20240228.pdf (3.45 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 sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Prospective patient-based data collection

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