Comparative effectiveness of heterologous and homologous primary- and booster SARS-CoV-2 vaccination schedules in the Nordic countries

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Study Finalised

Administrative details

EU PAS number

EUPAS46537

Study ID

48758

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Norway

Sweden

Study status

Finalised

Research institutions and networks

Institutions

Data Analytic Center (DAC), Danish Medicine Agency

Denmark

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Institution | **EU Institution/Body/Agency** | **ENCePP partner**

Danish Medicines Agency, Data Analytics Centre Axel Heides Gade 1, DK-2300 Copenhagen S, Denmark, University of Copenhagen, Department of Drug Design and Pharmacology, Pharmacovigilance Research Center, Faculty of Health and Medical Sciences Universitetsparken 2, DK-2100 Copenhagen Ø, Denmark, University of Southern Denmark, Faculty of Health Sciences,

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/01/2022

Actual: 26/01/2022

Study start date
Planned: 01/04/2022

Actual: 01/04/2022

Date of final study report
Planned: 26/09/2022

Actual: 26/08/2022

Sources of funding

- EMA

Study protocol

EMA_CVE_STUDYPROTOCOL_final_v1_.pdf (1.18 MB)

EMA_CVE_STUDYPROTOCOL_v1_1.pdf (1.19 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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The overall aim of this project is to provide combined and country-specific (Denmark, Finland, Norway and Sweden) estimates of covid-19 vaccination schedule effectiveness using comparative study designs.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Nationwide register-based study

Study drug and medical condition

Medical condition to be studied

COVID-19

COVID-19 immunisation

Population studied

Short description of the study population

The study cohort consist of all individuals aged 5 years or older at date of first vaccination identified from the nationwide registers including Denmark, Finland, Norway and Sweden during the study period of 27 December 2020 to 28 February 2022.

Inclusion criteria:

• having received at least the primary immunisation (i.e. 1. and 2. vaccine dose against covid-19) with either AZD1222, BNT162b2 or the mRNA-1273 vaccines (for the purpose of objective #5, being vaccinated was not an eligibility criterion),

• known residency within the specific country,

• and no positive reverse transcription polymerase chain reaction (PCR) test before the study period start and before receiving a 2. or 3. dose in the distinct

schedule evaluated.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 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

Other

Special population of interest, other

COVID-19 patients

Estimated number of subjects

19600000

Study design details

Outcomes

To provide comparative vaccination effectiveness (VE) estimates for: - Heterologous primary (2-dose) schedules compared to homologous primary (2-dose) schedules as well as heterologous booster (3-dose) schedules compared to homologous booster (3-dose) schedules. - And both heterologous and homologous booster (3-dose) schedules compared to heterologous and homologous primary (2-dose) schedules. - To provide comparative VE estimates

for selected schedules in the periods of Alpha, Delta and Omicron dominance (with variant specific endpoint information to the extent this is possible). - To explore a) waning of immunity comparing time-since vaccination periods within selected schedules and b) comparative waning comparing time-since vaccination across selected schedules.

Data analysis plan

Nationwide register-based cohort studies in Denmark, Finland, Norway and Sweden during the study period 27 December 2020 to 28 February 2022. We will compare schedules head-to-head and provide comparative VE estimates using survival analysis to estimate risk differences and risk ratios from adjusted survival curves. We will include adjustment for age, calendar period, sex, comorbidities and vaccination priority group.

Documents

Study results

EMA_CVE_study_report_240822-1-92.pdf (5.78 MB)

Study report

EMA_CVE_study_report_240822-93-219.pdf (7 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), other

Multiple nationwide demography and health care registers Denmark, Multiple nationwide demography and health care registers Finland, Multiple nationwide demography and health care registers Norway, Multiple nationwide demography and health care registers Sweden

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Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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