Vaccine Effectiveness, Burden and Impact Studies (VEBIS) - Healthcare worker cohort

First published: 04/04/2024

Last updated: 03/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000094

Study ID

1000000094

DARWIN EU® study

No

Study countries

- [ ] Croatia
- [ ] Estonia
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Latvia

- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Spain

Study description

Starting December 2021, ECDC-funded Vaccine Effectiveness, Burden and Impact (VEBIS) Framework Contract ECDC/2021/017 included the Lot 2: “Assessment of COVID-19 vaccine effectiveness among healthcare workers”. The VEBIS HCW VE cohort study included until 21 May 2023, 19 sites in 10 countries. Real-world VE studies can also answer questions about effectiveness by age group and risk factors, duration of vaccine protection, effectiveness of different vaccines, and effectiveness of the vaccine against new variants of SARS-CoV-2. The frequent testing independent of symptoms is especially relevant during the Omicron period, which is more associated with less severe or asymptomatic disease.

Study status

Ongoing

Research institutions and networks

Institutions

European Centre for Disease Prevention and Control

EpiConcept

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Study contact

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Primary lead investigator

Camelia Savulescu

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/10/2021

Study start date

Actual: 13/10/2021

Date of final study report

Planned: 31/10/2025

Sources of funding

- Other

More details on funding

Funding from European Centre for Disease Prevention and Control

Study protocol

Generic protocol for ECDC studies of COVID-19 vaccine effectiveness against confirmed SARS-CoV-2 using healthcare worker cohorts, version 1.0.pdf(1.05 MB)

Generic protocol for ECDC studies of COVID-19 vaccine effectiveness against confirmed SARS-CoV-2 using healthcare worker cohorts, version 3.0.pdf(852.03 KB)

Regulatory

Was the study required by a regulatory body?

No

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)

Data collection methods:

Primary data collection

Study design:

Prospective longitudinal multicentre cohort study among health workers eligible for vaccination.

Main study objective:

The primary objective of this study is to measure COVID-19 vaccine effectiveness (VE) amongst hospital HCWs eligible for vaccination against laboratory-confirmed SARS-CoV-2 infection.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BIMERVAX

COMIRNATY

JCOVDEN

NUVAXOVID

SPIKEVAX

VAXZEVRIA

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)

DAVESOMERAN

ELASOMERAN

IMELASOMERAN

RAXTOZINAMERAN

TOZINAMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN) Covid-19 vaccines

Covid-19 vaccines

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

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

covid-19, viral vector, non-replicating

(J07BN04) covid-19, protein subunit

covid-19, protein subunit

Medical condition to be studied

COVID-19

Population studied

Short description of the study population

The study population was recruited from hospital- based healthcare workers (HCWs) in participating hospitals, eligible for vaccination, with no contraindication to receive COVID-19 vaccine. HCWs included all categories of staff working in the hospitals and are defined as all staff involved or providing direct care to patients, who may not have provided direct care to the patient but who have had contact with the patient’s body fluids, potentially contaminated items or environmental surfaces present as well as those who may have been in the same area as patients.

HCW who have already been vaccinated against COVID-19 as part of the routine COVID-19 vaccine rollout could be included, as long as information can be collected about the vaccine brand(s), number of doses and dates of vaccination.

HCW who are not eligible for COVID-19 vaccination, or where vaccination is contra-indicated, or who have not signed an informed consent form for the winter season 2023/24 were not eligible to participate in the study and were excluded.

Age groups

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

3000

Study design details

Setting

EU/EEA hospital HCWs eligible for COVID-19 vaccination. The study should be conducted only after the study protocol is approved by the relevant ethical review committee. The study period begins any time after COVID-19 vaccines became available in each of the participating countries. The study period should ensure for all individuals enrolled a minimum follow-up of three months and longer if feasible. Follow-up time will also depend on the level of viral circulation.

Outcomes

The primary outcome was a confirmed SARS-CoV-2 infection detected by laboratory RT-PCR in any participant, regardless of symptoms.
Secondary outcomes included symptomatic COVID-19 defined as participants with confirmed SARS-CoV-2 infection detected by laboratory RT-PCR who reported 14 days before to 7 days after the first positive RT-PCR test: one or more of the symptoms or a set of clinical criteria to conform with the Influenza-like illness (ILI) and acute respiratory infection (ARI) case definition.

Data analysis plan

See protocol.

Documents

Interim analysis of COVID-19 vaccine effectiveness in healthcare workers, an EC...

Generic protocol for ECDC studies of influenza vaccine effectiveness against co...

Data management

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

Unknown