DARWIN EU® Effectiveness of COVID-19 vaccines on severe COVID-19 and post acute outcomes of SARS-CoV-2 infection

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Last updated: 09/12/2024

Study Finalised

Administrative details

EU PAS number

EUPAS107615

Study ID

107616

DARWIN EU® study

Yes

Study countries

- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

COVID 19 vaccines were authorised for use in the European Union, and these vaccines, and any future adapted vaccines, would therefore benefit from post authorisation studies to provide real world evidence to guide regulatory and vaccination policies.

This study will aim to assess 1 the effectiveness and waning of effectiveness of COVID 19 vaccination for the prevention of severe COVID 19 related outcomes, 2 effectiveness of COVID 19 vaccination for the prevention of all cause mortality in the 3 and 6 months following discharge for COVID 19 related hospitalization as well as 3 effectiveness of COVID 19 vaccination for the prevention of post COVID 19 complications, namely of new onset type 1 Diabetes Mellitus, new onset type 2 Diabetes Mellitus, and cardiovascular events in the 12 months after a SARS CoV 2 infection.

Study status

Finalised

Research institutions and networks

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- ☐ Belgium
- ☐ Croatia
- ☐ Denmark
- ☐ Estonia
- ☐ Finland

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Annika Jodicke

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/07/2023

Actual: 26/07/2023

Study start date
Planned: 01/01/2021

Actual: 01/01/2021

Date of final study report
Planned: 31/01/2023

Actual: 01/07/2024

Sources of funding

- EMA

Study protocol

DARWIN_EU_D2.2.3_Protocol_P2-C3-002_V2.1_Public.pdf(1.24 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 topic:

Human medicinal product

Study type:

Non-interventional study

Study design:

Population-level cohort studies

Main study objective:

To assess the effectiveness and waning of effectiveness of COVID-19 vaccination for the prevention of severe COVID-19 related outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

COMIRNATY

SPIKEVAX

Name of medicine, other

COVID-19 vaccines BNT162b2 and mRNA-1273

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

Medical condition to be studied

COVID-19

Additional medical condition(s)

Severe COVID-19 and post-acute outcomes of SARSCoV-2 infection

Population studied

Short description of the study population

All subjects aged 12 years and older, with at least 365 days of data availability before index date (ID) [ID defined as the date of the latest vaccine dose administered] AND data availability from 12/2020 onwards (i.e. the time when the roll-out of the vaccination campaign started) in the respective database will be included.

Age groups

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)

Estimated number of subjects

10190000

Study design details

Outcomes

COVID-19 related hospitalisation or COVID-19 related death. To assess the effectiveness of COVID-19 vaccination for the prevention of post-acute all-cause mortality in the 3- and 6-months following discharge for COVID-19 related hospitalisation.

Data analysis plan

All analyses will be conducted separately for each database and will be carried out in a federated manner allowing analyses to be run locally without sharing patient level data. Before sharing the study package test runs of the analytics will be performed on a subset of the data sources and quality control checks will be performed.

After all the tests are passed see section 11 Quality Control the final package will be released in a version controlled study repository for execution against all the participating data sources.

The data partners will locally execute the analytics against the OMOP CDM in R Studio and review and approve the by default aggregated results. They will

then be made available to the Principal Investigators and study team in the Digital Research Environment.
All results were locked and timestamped for reproducibility and transparency.

Documents

Study report

DARWIN EU_Report_P2-C3-002_CoVVaccineEffectiveness_V5.pdf(2.97 MB)

P2-C3-002 Executive Summary_V3.pdf(344.44 KB)

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)

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No