

id.DRIVE (former COVIDRIVE) study of brand-specific COVID-19 vaccine effectiveness against severe COVID-19 disease in Europe

First published: 02/08/2021

Last updated: 01/10/2025

Study

Ongoing

Administrative details

EU PAS number

EUPAS42328

Study ID

49374

DARWIN EU® study

No

Study countries

☐ France

☐ Germany

☐ Italy

- ☐ Spain
 - ☐ United Kingdom
-

Study description

This Master Protocol describes a non-interventional study to estimate the effectiveness of coronavirus disease 2019 (COVID-19) vaccines against severe COVID-19 in Europe.

The study is a multi-country, hospital-based, case-control study with test-negative controls (test-negative case-control design, TNCC).

This Master Protocol will be used to create Study Requestor-specific protocols that meet the requirements of the Study Requestors (Pharmaceutical Company Partners) and to create site-specific protocols that reflect the data collection and requirements at the specific study sites (Study Contributors).

This Master Protocol is set up to harmonise study methods (e.g., study objectives, subject inclusion/exclusion criteria, case definitions, exposures, outcomes, and data collection) and to mutualise healthcare providers/study site resources.

Study status

Ongoing

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

- ☐ Belgium
- ☐ Colombia

- ☐ Netherlands
- ☐ South Africa
- ☐ Thailand
- ☐ United States

First published: 07/11/2022

Last updated: 21/02/2025

Institution

Laboratory/Research/Testing facility

Non-Pharmaceutical company

ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

- ☐ Spain

First published: 01/02/2024

Last updated: 05/11/2024

Institution

University Hospital Vall d'Hebron (HUVH)

- ☐ Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

Imperial College London

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

Valencia Hospital Network for the Study of
Influenza and Other Respiratory Viruses (VAHNSI)
Germans Trias i Pujol University Hospital
Hospital Clínico Universitario de Santiago de
Compostela
Hospital Universitario La Paz

Centro Interuniversitario per la Ricerca
sull'Influenza e le altre Infezioni (CIRI-IT)

Universitätsklinikum Ulm
Charité - Universitätsmedizin Berlin

Manchester University NHS Foundation Trust
(MFT)

NHS Lothian

Hôpitaux Universitaires Henri-Mondor
Centre Hospitalier Annecy Genevois

Networks

id.DRIVE (former COVIDRIVE)

- ☐ Austria
- ☐ Belgium
- ☐ Croatia
- ☐ Czechia
- ☐ Denmark
- ☐ France
- ☐ Germany
- ☐ Iceland
- ☐ Italy
- ☐ Poland
- ☐ Romania
- ☐ Spain

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Last updated: 29/02/2024

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kaatje Bollaerts

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/08/2021

Study start date

Planned: 15/08/2021

Actual: 08/09/2021

Date of final study report

Planned: 01/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, Johnson & Johnson, Novavax, Valneva, Pfizer

Study protocol

[COVIDRIVE_TND-VE_MasterProtocol_v3.1.pdf](#) (3.85 MB)

[COVID-19 Vaccine Effectiveness protocol v7.0_21 Feb 2025.pdf](#) (727.1 KB)

[CVE_Master Protocol v6.0_21 Mar 2024.pdf](#) (883.8 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

[Link to id.DRIVE.eu](#)

[Interim analysis AstraZeneca \(AZD1222, ChAdOx1 nCoV-19\)](#)

[Final analysis AstraZeneca \(AZD1222, ChAdOx1 nCoV-19\)](#)

[Final analysis Janssen \(JCOVDEN, Ad26.COV2.S\)](#)

[Interim analysis Pfizer \(BNT162b2 XBB.1.5-adapted vaccine\)](#)

[Interim analysis Pfizer \(BNT162b2 XBB.1.5-adapted vaccine\)](#)

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This study is a multi-country, multi-centre, hospital-based case-control study with test-negative controls (TNCC design).

A combination of primary and secondary data collection will be used to obtain the relevant data.

Main study objective:

To estimate brand-specific COVID-19 vaccine effectiveness (CVE) against hospitalisation due to laboratory-confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in SARI patients who have received [vaccine dose of interest], compared to [selected comparator group].

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Name of medicine

COMIRNATY

COVID-19 VACCINE (INACTIVATED, ADJUVANTED)

JCOVDEN

NUVAXOVID

VAXZEVRIA

Name of medicine, other

COVID-19 vaccine (Ad26.COV2-S [recombinant])

COVID-19 vaccine (ChAdOx1-S [recombinant])

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)

FAMTOZINAMERAN

RAXTOZINAMERAN

RILTOZINAMERAN

TOZINAMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN) Covid-19 vaccines

Covid-19 vaccines

Medical condition to be studied

Respiratory tract infection

Population studied

Short description of the study population

The study population consists of individuals (patients), presenting at the participating hospitals during the study period, who were ever eligible for COVID-19 vaccination following the national/regional immunisation recommendations prior to hospital admission AND from whom informed consent is obtained (alternative: informed consent from legally acceptable representative) AND are hospitalised (=person admitted to the hospital with overnight stay) AND meet the severe acute respiratory infection (SARI) case definition but HAVE NOT BEEN hospitalised with COVID-19 within 3 months prior to the current admission and DO NOT HAVE any contraindication for swabbing and DID NOT receive their last vaccine dose with any other than EMA-approved COVID-19 vaccine brand (EMA approval status at time of hospitalisation).

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)

Estimated number of subjects

15000

Study design details

Setting

Hospitals

Comparators

Unvaccinated or not recently vaccinated patients

Outcomes

The outcome of interest for the primary analysis will be SARS-CoV-2 detection in patients hospitalised with SARI symptoms.

SARS-CoV-2 infection should be laboratory-confirmed by reverse transcription polymerase chain reaction (RT-PCR) or another RNA amplification system with at least the same sensitivity as RT-PCR (e.g., transcription-mediated amplification (TMA)).

As the SARS-CoV-2 testing practices might change over time, the test requirement for confirmation of COVID-19 disease might be revisited. The impact of such revisions on the potential for disease misclassification will be considered.

Data analysis plan

A SAP is developed prior to the conduct of the analysis.

The SAP specifies all statistical analyses conducted, and includes tables shells and mock figures.

Summary results

See interim analyses by AstraZeneca and Pfizer (Study publications section)

See final analyses by AstraZeneca and Janssen (Study publications section)

Documents

Study results

[COVIDRIVE_Pfizer interim.pdf](#) (878.86 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 sources (types)

[Electronic healthcare records \(EHR\)](#)

[Laboratory tests and analyses](#)

[Other](#)

Data sources (types), other

Vaccination registries, vaccination cards, medical records, laboratory data (RT-PCR and genetic variants).

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction