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: 27/02/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS42328

Study ID

49374

DARWIN EU® study

No

Study countries

- ☐ 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)

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

Germans Trias i Pujol University Hospital

Universitätsklinikum Ulm

Universitätsklinikum Frankfurt

Ospedale Luigi Sacco

Hospital Clínic de Barcelona

Hospital Clínico Universitario de Santiago de

Compostela

Hospital Universitario La Paz

Manchester University NHS Foundation Trust (MFT)

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

Network **ENCePP partner**

Contact details

Study institution contact

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Study contact

kaatje.bollaerts@p-95.com

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: 31/12/2025

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)

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)

Methodological aspects

Study type

Study type list

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) VALNEVA (--) - SUSPENSION FOR INJECTION

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 analysis by AstraZeneca (Study publications section)
See final analyses by AstraZeneca (Study publications section)

Documents

Study results

COVIDRIVE_Pfizer interim.pdf(878.86 KB)

Data management

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