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: 05/06/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49374

EU PAS number
EUPAS42328

Study ID
49374

DARWIN EU® study
No

Study countries
Austria
Germany
Italy
Spain

Study description
This protocol details a non-interventional study to estimate the effectiveness of COVID-19 vaccines against COVID-19-related hospitalisations through the COVIDRIVE partnership. In addition, the potential for vaccine-associated enhanced disease (VAED) will be studied as part of this vaccine effectiveness study as VAED relates to the efficacy/effectiveness outcomes. This is a prospective, multi-centre, hospital-based, case-control study with test-

negative controls (test-negative case-control design). Data will be collected through a wide network of hospitals located in several European countries and the UK.

Study status
Ongoing

Research institution and networks

Institutions

P95 Epidemiology & Pharmacovigilance

Belgium
Colombia
Netherlands
South Africa
Thailand
United States
First published: 07/11/2022
Last updated
09/04/2024

Institution
Non-Pharmaceutical company
Laboratory/Research/Testing facility
ENCePP partner

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

Spain
First published: 01/02/2024
Last updated
01/02/2024

Institution

University Hospital Vall d'Hebron (HUVH)

Spain
First published: 01/02/2024
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01/02/2024

Institution
Hospital/Clinic/Other health care facility
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
Klinik Favoriten
St Pierre University Hospital
Universitair Ziekenhuis Antwerpen
Grand Hôpital de Charleroi
Ospedale Luigi Sacco
Hospital Clínic de Barcelona
Hospital Clínico Universitario de Santiago de Compostela
Universitätsklinikum Frankfurt
Universitätsklinikum Ulm
Universitätsklinikum Freiburg

Networks

id.DRIVE (former COVIDRIVE)

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

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Network | ENCePP partner

Contact details

Study institution contact
Kaatje Bollaerts
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:
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)

Protocol_Master Final Protocol_V5.0_18 Sep 2023-3.pdf(957.04 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

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 and secondary data collection

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

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

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)

Documents

Study publications
Interim analysis AstraZeneca

Data management

Data sources

Data sources (types)
Electronic healthcare records (EHR)
Laboratory data
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