id.DRIVE study of brand-specific respiratory syncytial virus (RSV) vaccine effectiveness in Europe

First published: 01/03/2024

Last updated: 01/10/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000035

EU PAS number

EUPAS1000000035

Study ID

1000000035

DARWIN EU® study

No

Study countries

☐ France

- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

This is a European, non-interventional study to estimate the effectiveness of vaccines against respiratory syncytial virus (RSV). Of interest is the effectiveness against hospitalisation with severe acute respiratory infection (SARI) caused by RSV.

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

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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

Hôpitaux Universitaires Henri-Mondor

Manchester University NHS Foundation Trust (MFT)

NHS Lothian

Networks

id.DRIVE (former COVIDRIVE)

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

First published: 06/09/2021

Last updated: 29/02/2024

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: 15/03/2024

Study start date
Planned: 01/06/2024

Actual: 29/08/2024

Date of final study report
Planned: 31/05/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

RSV_Master Protocol V2.0_07 Jun 2024.pdf(994.21 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

https://iddrive.eu

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

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 RSV vaccine effectiveness (VE) against hospitalisation due to laboratory-confirmed RSV infection in severe acute respiratory infection (modified SARI) older adult patients.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Name of medicine

ABRYSVO

Name of medicine, other

Respiratory syncytial virus vaccine (bivalent, recombinant)

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

Severe acute respiratory syndrome

Population studied

Short description of the study population

The study population consists of hospitalised "modified severe acute respiratory infection (SARI)"* ≥60 year-old patients.

A "modified SARI"* patient is a person hospitalised primarily for a suspicion of a respiratory infection with at least one of the following symptoms:

• cough,

• shortness of breath,

• fever (≥38 C^0)

with symptom onset within the last 10 days prior to hospital admission.

*This SARI definition is modified from the latest European Centre for Disease Prevention and Control (ECDC) case definition [EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (2021). ECDC Technical report: Core protocol for ECDC studies of COVID-19 vaccine effectiveness against hospitalisation with Severe Acute Respiratory Infection laboratory-confirmed with SARS-CoV-2, version 1.0, 2021].

Study design details

Setting

Hospitals

Outcomes

The outcome of interest for the primary analysis will be RSV detection in patients hospitalised with symptoms consistent with the modified ECDC SARI definition.

RSV infection must be laboratory-confirmed by reverse transcription polymerase chain reaction (RT-PCR) or another ribonucleic acid (RNA) amplification system with at least the same sensitivity as RT-PCR (e.g., transcription-mediated amplification [TMA]). RT-PCR assays must be used for the detection of at least RSV, SARS-CoV-2, and influenza.

The secondary outcomes in patients hospitalised with modified SARI symptoms include:

• detection of RSV subtypes A and B

• detection of RSV genotypes

• modified SARI severity level of study participants (both cases and controls), including respiratory support severity level

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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.

Documents

Link to id.DRIVE.eu

Data management

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