id.DRIVE surveillance study of respiratory pathogens in adults hospitalised for severe acute respiratory infection (SARI) across Europe

First published: 28/02/2024

Last updated: 30/09/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000012

Study ID

1000000012

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

☐ Spain

☐ United Kingdom

Study description

id.DRIVE’s Study Network will be leveraged to continuously monitor severe acute respiratory infection (SARI)-causing pathogens (e.g., severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza, and respiratory syncytial virus [RSV]), including virological and clinical trends, as well as burden of disease (e.g., pathogen-specific morbidity; in-hospital mortality).
The surveillance of additional pathogens allows for study preparedness, with the potential to perform feasibility assessments for future impact and effectiveness studies within the id.DRIVE Study Network.

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

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

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Network **ENCePP partner**

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

Actual: 14/12/2023

Study start date

Planned: 01/06/2024

Actual: 29/08/2024

Date of final study report

Planned: 31/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, Pfizer

Study protocol

Surveillance study_Protocol_V1.0_21 Mar 2024.pdf(832.64 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

Link to id.DRIVE.eu

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study topic, other:

Surveillance of respiratory pathogens in Europe

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Non-interventional multi-country, multi-centre, hospital-based surveillance study.

Main study objective:

This surveillance study aims to establish active surveillance for hospitalised SARI cases in adults in Europe.

Primary objectives:

1. Proportion of laboratory samples positive for each viral respiratory pathogen of interest
2. Characterisation of adult SARI patients overall and by pathogen

Study Design

Non-interventional study design

Other

Study drug and medical condition

Medical condition to be studied

Severe acute respiratory syndrome

Population studied

Short description of the study population

Adults aged 18 years and older (patients), presenting at the participating hospitals during the study period, who are willing and able to provide informed consent (or alternatively, informed consent is obtained form the patient´s legally acceptable representatitve) AND who are hospitalised and meet the SARI patient definition.

A SARI patient is defined as a hospitalised person with a suspicion of a respiratory infection with at least one of the following symptoms:

• cough

• fever (≥ 38 C°)

• shortness of breath

• sudden onset of anosmia, ageusia or dysgeusia

with symptom onset within the last 14 days prior to hospital admission.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

Hospitals

Outcomes

The outcome of interest for the primary objectives will be laboratory-confirmed infection with one of the viral respiratory pathogens of interest in patients hospitalised with SARI symptoms, and laboratory-confirmed co-infection for the secondary objective (prevalence of co-infection with the viral respiratory pathogens of interest, in adult patients hospitalised with SARI, and the impact on healthcare utilisation outcomes [level of severity, hospital discharge destination, length of hospital stay]).

Pathogen-specific SARI incidences will be calculated to address the first exploratory objective (pathogen-specific SARI incidences and description of trends in hospitalised adults [time period, country, level of severity]). The denominator will be based on the sum of the catchment populations covered by the Study Contributors.

For the second exploratory objective, feasibility assessments for future respiratory disease impact and effectiveness studies will be made.

Data analysis plan

A statistical analysis plan (SAP) is developed prior to the conduct of the analysis. The SAP specifies all statistical analyses, including sensitivity analyses, to be conducted and includes table shells and mock figures.

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

Medical records, laboratory records, vaccination registries etc.

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