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

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000012

EU PAS number
EUPAS1000000012

Study ID
1000000012

DARWIN EU® study
No

Study countries
Belgium
Germany
Italy
Spain

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
Planned

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
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01/02/2024

Institution

University Hospital Vall d'Hebron (HUVH)

Spain
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01/02/2024

Institution

Educational Institution | Hospital/Clinic/Other health care facility

Valencia Hospital Surveillance Network for the Study of Influenza and Other Infectious Diseases (VAHNSI)
Le Centre Hospitalier Universitaire St Pierre (CHU St Pierre)
Universitair Ziekenhuis Antwerpen (UZA)
Centro Interuniversitario per la Ricerca sull'Influenza e le altre Infezioni Trasmissibili (CIRI-IT)
Hospital Universitario Germans Trias i Pujol (GTPUH)
Hospital Clínic de Barcelona
Hospital Clínico Universitario de Santiago de Compostela
Universitätsklinikum Freiburg
Universitätsklinikum Frankfurt
Universitätsklinikum Ulm
Ospedale Luigi Sacco

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
Actual:
14/12/2023

Study start date
Planned:
01/06/2024

Date of final study report
Planned:
31/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, Pfizer

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 and secondary data collection

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

Data sources

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