European study of COVID-19 vaccine effectiveness against hospitalised SARI patients laboratory-confirmed with SARS-CoV-2 (I-MOVE-COVID VE hospital study)

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Study Planned

Administrative details

EU PAS number

EUPAS39683

Study ID

39684

DARWIN EU® study

No

Study countries

Austria

Belgium

France

Germany
Italy
Netherlands
Norway
Portugal
Spain
Switzerland
United Kingdom

Study description

Multicentre European study at hospital level, measuring vaccine effectiveness using a test-negative design. Participating hospitals recruit Severe Acute Respiratory Infection patients: those testing positive for SARS-CoV-2 are cases and those testing negative are the controls

Study status

Planned

Research institutions and networks

Institutions

EpiConcept

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Angie Rose

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/03/2020

Study start date
Planned: 01/02/2021

Date of final study report
Planned: 01/03/2022

Sources of funding

- EU institutional research programme
- Other

More details on funding

European Commission, Public Health Institutes

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://www.imoveflu.org/wp-content/uploads/2021/02/08feb2021_draft_generic_VE_protocol_hospital-based_COVID-19_v07.pdf,,DOI: 10.5281/zenodo.4555315

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To measure product-specific COVID-19 vaccine effectiveness

Study Design

Non-interventional study design

Case-control

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

1000

Study design details

Outcomes

SARI laboratory confirmed as COVID-19 / SARS-CoV-2 infection, SARS-CoV-2 variant specific

Data analysis plan

Test-negative design. Vaccine effectiveness: adjusted 1-OR*100 Study site as fixed effect. Time adjusted. Stratification by age group, chronic condition. Vaccine effectiveness over time.

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)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No