COVID-19 vaccine effectiveness at primary care level in Europe: generic protocol (I-MOVE-COVID primary care VE)

First published: 27/02/2021

Last updated: 14/03/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41151

EU PAS number

EUPAS39679

Study ID

41151

DARWIN EU® study

No

Study countries

☐ France

- [ ] Ireland
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom (Northern Ireland)

Study description

Multicentre European test-negative design at primary care level, measuring COVID-19 vaccine effectiveness

Study status

Planned

Research institutions and networks

Institutions

EpiConcept

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Influenza – Monitoring Vaccine Effectiveness in Europe (I-MOVE)

- [ ] Belgium
- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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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

Esther Kissling

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 National institutes

Study protocol

I-MOVE-COVID-19 primary care COVID-19 vaccine effectiveness protocol v2.2.pdf(937.65 KB)

I-MOVE-COVID-19 primary care COVID-19 vaccine effectiveness protocol v2.3.pdf(926.99 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://www.imoveflu.org/wp-content/uploads/2021/02/I-MOVE-COVID-19-primary-care-COVID-19-vaccine-effectiveness-protocol-v2.2.pdf

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 COVID vaccine effectiveness against acute respiratory infection laboratory confirmed as SARS-CoV-2

Study Design

Non-interventional study design

Case-control

Other

Non-interventional study design, other

Sentinel sites

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

ARI laboratory confirmed as SARS-CoV-2, Variant specific

Data analysis plan

Vaccine effectiveness = 1-adjusted OR*100 Log reg adjusted OR comparing ARI cases testing positive for SARS-CoV-2 to ARI patients testing negative. Study site as fixed effect. Time adjusted OR stratified by age group, chronic condition, period of time. Brand specific.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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