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 institution 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
First published: 22/04/2013
Last updated 14/05/2013
Network ENCePP partner

Contact details

Study institution contact

Valenciano Marta
Study contact
m.valenciano@epiconcept.fr
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