# 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

**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

**First published:** 22/04/2013

**Last updated:** 14/05/2013

**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

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**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)

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**Estimated number of subjects**

1000

## Study design details

**Outcomes**

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

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**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

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No