ACCESS template protocols for effectiveness of COVID-19 vaccines (ACCESS-effectiveness)

First published: 31/01/2021

Last updated: 23/05/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39316

EU PAS number

EUPAS39289

Study ID

39316

DARWIN EU® study

No

Study countries

☐ Belgium

- [ ] Denmark
- [ ] France
- [ ] Italy
- [ ] Netherlands
- [ ] Spain

Study description

This registration comprises 2 template protocols from the ACCESS project to monitor COVID-19 vaccine effectiveness. They differ as regards the methods and the data collection. These template protocols can be adapted to the local situation 1. Test negative case control design based on primary data collection (written by Fisabio) 2. Retrospective cohort study to monitor effectiveness of COVID-19 vaccine (written by RTI-HS)

Study status

Finalised

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

- [ ] Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

Last updated: 22/09/2020

Network ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

- [ ] Netherlands

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/05/2020

Actual: 21/05/2020

Study start date

Planned: 22/05/2020

Actual: 22/05/2020

Date of final study report

Planned: 15/12/2020

Actual: 15/12/2020

Sources of funding

- EMA

Study protocol

3e. Protocol_ACCESS Effectiveness TND Protocol.pdf(1.12 MB)

3f. Protocol_ACCESS_COVID-19 EHR Vaccine Effectiveness Protocol Template.pdf(1.5 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess COVID-19 vaccine effectiveness

Study Design

Non-interventional study design

Case-control

Cohort

Other

Non-interventional study design, other

Sentinel sites

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07X) OTHER VACCINES

OTHER VACCINES

Medical condition to be studied

SARS-CoV-2 test positive

Population studied

Short description of the study population

Cohort study: This study should be conducted in populations where COVID-19 vaccine product is approved and recommended for use.

Case-control: All-ages patients admitted to the hospital, through the Emergency Department or transferred from other hospitals or health facilities, fulfilling the ECDC case definition for COVID-19 disease.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

100

Study design details

Data analysis plan

Estimation of vaccine effectiveness

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug registry

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