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 institution 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 23/05/2024

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 and secondary data collection

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

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 data (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