FOUR-YEAR EFFECTIVENESS OF COVID-19 VACCINES AGAINST SEVERE DISEASE AND ASYMPTOMATIC INFECTION: THE COVIDVAC@SPAIN STUDY

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Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS43186

Study ID

43187

DARWIN EU® study

No

Study countries

Spain

Study description

Retrospective observational epidemiological study

Study status

Planned

Research institutions and networks

Institutions

Hospital La Paz

First published: 01/02/2024

Last updated: 01/02/2024

Institution

School of Medicine

Clinical Pharmacology Department, Hospital La Paz, School of Medicine

Spain

First published: 24/10/2022

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

Networks

SCReN

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Antonio J Carcas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2021

Study start date

Planned: 04/10/2021

Date of final study report

Planned: 30/09/2025

Sources of funding

- Other

More details on funding

Instituto de Salud Carlos III

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

Estimate: 1) vaccine effectiveness (VE) of approved COVID vaccines in preventing asymptomatic infection, 2) the viral replication difference in

vaccinated vs non-vaccinated subjects, 3) the VE of approved COVID vaccines in preventing severe outcomes in persons who require hospitalization, 4) if the VE from objective #3 varies according to SARS-CoV-2 variants or strains carrying specific mutation

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective observational epidemiological study

Study drug and medical condition

Medical condition to be studied

COVID-19 immunisation

Population studied

Age groups

- 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

33.600

Study design details

Outcomes

Substudy A: SARS-CoV-2 PCR positive/negative results Substudy B: • Maximum level of oxygen support required • ICU admission (and duration) • Mechanical ventilation (and duration) • Pulmonary embolism • Death or discharge hospitalization • Total duration of hospital stay, Interaction between vaccination. Variant-specific VE

Data analysis plan

For main objective #1, multivariate logistic regression will be used. For main objective #2 a sub-analysis of positive cases will be carried out and mean Ct values will be compared between vaccinated and non-vaccinated groups using generalized linear models. For main objectives #3 and #4, longitudinal data will be analysed using either multivariate Poisson models or survival analysis and Cox regression. For secondary objectives #1, #2 and #3, interaction between vaccination and independent variables will be tested, and stratified estimations in groups defined by vaccination schedule, age, sex, previous SARS-CoV-2 infection and comorbidities will be performed.For secondary objective #4 all project data will be pooled and an interaction between study period (selection-round) and vaccination status will be tested to analyse statistically significant variation in VE. Stata v15.0.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Medical records: retrospective study

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