Effectiveness of the Novavax COVID-19 Vaccine in Reducing Clinically Defined Severe SARS-CoV-2 Infection in Individuals ≥ 12 Years of Age in the United States

First published: 03/07/2023

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105522

EU PAS number

EUPAS105521

Study ID

105522

DARWIN EU® study

No

Study countries

United States

Study description

Observational retrospective comparative effectiveness database study to evaluate the effectiveness of the Novavax COVID-19 vaccine using the HealthVerity database. This Post-Authorization Effectiveness Study (PAES) will assess the effectiveness of a two-dose primary series Novavax COVID-19 vaccine in preventing clinically defined severe SARS-CoV-2 infection (i.e. COVID-19-associated hospitalization) compared to a matched contemporaneous cohort of unvaccinated individuals. Further, the effectiveness of the Novavax COVID-19 vaccine as a booster dose in preventing COVID-19 associated hospitalization compared to a matched contemporaneous cohort of eligible, but non-boosted individuals will be examined.

Study status

Ongoing

Research institutions and networks

Institutions

Aetion

Spain

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Institution | Other | ENCePP partner

Contact details

Study institution contact

Matthew Rousculp

Study contact

mrousculp@novavax.com

Primary lead investigator

Matthew Rousculp

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/12/2021

Study start date

Actual: 13/12/2018

Date of final study report

Planned: 24/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novavax

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

2019nCoV-403

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

1.1: Assess the annual seasonal effectiveness of a two-dose primary Novavax COVID-19 vaccine series in reducing COVID-19-associated hospitalizations compared to unvaccinated individuals. 1.2: Assess the annual seasonal effectiveness of a Novavax COVID-19 vaccine booster dose in reducing COVID-

19-associated hospitalization, compared to individuals eligible to receive a booster but not received o

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine, other

Novavax

Population studied

Age groups

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

10

Study design details

Outcomes

COVID-19 associated hospitalization, COVID-19 associated hospitalization with ICU admission

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Data analysis plan

Relevant descriptive and comparative analyses will be performed in either the validated AEP or R, using the most recent versions available at the time of analysis. All study objectives (Primary, Secondary, and Exploratory) will utilize only closed claims data to ensure that we have full capture of the individual's interactions with the healthcare system.

Data management

Data sources

Data source(s), other

HealthVerity United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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