Safety of the Novavax COVID-19 vaccine in England using a self-controlled case series design: A post-authorisation safety study using data from the Clinical Practice Research Datalink (CPRD) Aurum and linked databases

First published: 14/03/2023

Last updated: 14/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS103858

Study ID

103859

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Novavax developed a COVID-19 vaccine (NuvaxovidTM vaccine) which has been approved for use by the Medicines and Healthcare products Regulatory Agency (MHRA) to prevent COVID-19 caused by the SARS-CoV-2 virus in individuals 12 years of age and older. The Clinical Practice Research Datalink (CPRD) Aurum primary care and linked secondary care and mortality data will be used to assess the risk of select adverse events of interest (AESI) in patients after vaccination with the NuvaxovidTM vaccine. A self-controlled case series (SCCS) will make within-person comparisons of the incidence of AESI in pre-specified risk windows following any dose of the NuvaxovidTM vaccine with incidence in a post-vaccination control window. Secondary objectives will compare incidence after receipt of a first dose, completion of a two-dose primary series, receipt of a booster dose, and among subgroups of interest after any dose.

Study status

Planned

Research institutions and networks

Institutions

Dr. Sonia Coton

Contact details

Study institution contact

Nicole Baker nibaker@novavax.com

Study contact

nibaker@novavax.com

Primary lead investigator

Sonia Coton

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/10/2021

Study start date

Planned: 31/03/2023

Date of final study report

Planned: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novavax, Inc

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

2019nCoV-402

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate the risk of select AESI following vaccination with the NuvaxovidTM vaccine using a self-controlled case series design.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Medicinal product name

NUVAXOVID

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)

Special population of interest

Immunocompromised

Estimated number of subjects

10686

Study design details

Outcomes

The risk of select AESI following vaccination with any dose of NuvaxovidTM vaccine. The risk of select AESI following vaccination with NuvaxovidTM vaccine after receipt of a first dose, completion of a two-dose primary series, receipt of a booster dose, and among subgroups of interest after any dose.

Data analysis plan

The primary and secondary objectives will be analyzed using Conditional Poisson regression modelling to estimate incident rate ratios for each AESI.

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 source(s)

Clinical Practice Research Datalink

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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