Real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England. (RAVEN)

First published: 11/10/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43571

Study ID

50480

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This is a retrospective cohort study to assess the real world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England. The study is using linkage of the English national databases on COVID-19 vaccination, testing, medical records, hospitalization, and death. The analysis will primarily look at both doses, though the study will also report on single dose and booster doses.

Study status

Finalised

Contact details

Study institution contact

Clinical Study Information Center AstraZeneca
information.center@astrazeneca.com

Study contact

information.center@astrazeneca.com

Primary lead investigator

Simon de Lusignan

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/05/2021

Study start date

Actual: 23/08/2021

Data analysis start date
Actual: 06/09/2021

Date of final study report
Planned: 25/01/2023

Actual: 20/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D8111R00007-csp-v1_Redacted2.pdf (326.63 KB)

d8111r00007-csp-v3_Redacted.pdf (425.51 KB)

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

D8111R00007

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

This is a retrospective cohort study to assess the real world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England. The study is using linkage of the English national databases on COVID-19 vaccination, testing, medical records, hospitalization, and death.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational retrospective study

Study drug and medical condition

Medical condition to be studied

COVID-19

COVID-19 immunisation

Additional medical condition(s)

COVID-19/SARS-CoV-2 infection

Population studied

Short description of the study population

The study involved individuals who had received at least one dose of AstraZeneca or another COVID-19 vaccine from January 2021 or December 2020, and those in England who were not vaccinated with any covid-19 vaccine at the time of matching to an individual vaccinated with AstraZeneca or ‘other’ covid-19 vaccine.

Inclusion Criteria:

1. For the vaccinated arms:

- Any COVID-19 vaccination at the index date
- Have continuous data coverage for the COVID-19 infection datasets, i.e.

Second Generation Surveillance System (SGSS) and National Pathology Exchange (NPEX) from their initiation for history of prior COVID-19 infection
 Have continuous data coverage in other linked databases for a minimum of 12 months prior to the index date for assessment of baseline variables including socio-economic status, comorbidities, and follow-up of outcome events.

2. For the control arms:
 Eligible for any COVID-19 vaccination based on age at the index date for the concurrent control individuals.
 Have continuous data coverage for the COVID-19 infection datasets, i.e. SGSS and NPEX from their initiation for history of prior COVID-19 infection
 Have continuous data coverage in other linked databases for a minimum of 12 months prior to the index date for assessment of baseline variables including socio-economic status, comorbidities, and follow-up of outcome events.
 People who have not (yet) received any COVID-19 vaccine (Oxford/AstraZeneca, Pfizer, or Moderna COVID-19 vaccine) recorded in their GP record or in NIMS. They will be used as concurrent controls. However, they will be censored at date of vaccination and, then may re-enter the study as newly vaccinated individuals.

Exclusion Criteria:
 Primary analysis: People with a history of COVID-19 infection (confirmed by reverse transcriptase polymerase chain reaction (RT-PCR) or not) prior to vaccination. This group of people is not excluded in the sensitivity analysis.

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

Renal impaired

Estimated number of subjects

25400000

Study design details

Outcomes

The primary outcomes are COVID-19 related hospitalization, Intensive Care Unit (ICU) admission, and death., The following outcomes will be secondary: any positive SARS-CoV-2 test, medically attended COVID-19, COVID-19 related emergency department visit, HCRU related to COVID-19 and associated cost, breakthrough case, time to vaccine waning, and long COVID.

Data analysis plan

We will conduct a retrospective cohort analysis to assess vaccine effectiveness (VE). To carry out the analysis, unvaccinated persons will be matched each week (if feasible) to the vaccinated individuals by age, gender, general practitioner (GP) practice (or NHS region), and comorbidity. For each outcome event and for each study cohort, the number of first events, total person-years for the event, number of first events per person-years (rate), the rate ratio (RR) and the VE, calculated as (1 – RR)) will be presented. This will also be provided per age group and per frailty score. Finally, VE will also be provided in shorter periods after dose 1, and between the doses, and by presence of comorbidities.

Poisson regression will be used to estimate rates using the matched dataset, adjusting for the matching variables and body mass index (BMI), smoking, prescribed medications, and frailty score.

Documents

Study results

CSR Synopsis_Final_16Oct_all Redacted.pdf (132.35 KB)

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)

Administrative healthcare records (e.g., claims)

Drug registry

Electronic healthcare records (EHR)

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