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

**First published:** 11/10/2021

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Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/50480

**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

**Study contact**

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**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

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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**Non-interventional study design, other**

Observational retrospective study

## Study drug and medical condition

**Medical condition to be studied**

COVID-19

COVID-19 immunisation

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**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.

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**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

## 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