Post-authorisation active surveillance of the Safety of COVID-19 Vaccine AstraZeneca (AZD-1222) in the UK: A consortium study

First published: 05/11/2021

Last updated: 24/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44035

Study ID

44096

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study is a non-interventional post-authorisation active surveillance study to monitor the utilisation and safety of COVID-19 vaccine AstraZeneca (AZD-1222) in the UK. Vaccinees will be recruited via the mass vaccination programme through various vaccination sites and other methods of recruitment will be used where appropriate (e.g. through social media, newspapers and local radio stations). Informed consent will be obtained. Baseline information and any symptom/condition following vaccination reported by the vaccinee will be collected. Further information related to serious and AESIs will be captured from General Practitioners (GPs) and/or healthcare professionals (HCPs) where appropriate. Vaccinees will be contacted at various time points through text message, email, or phone and asked whether they experienced an adverse event. If an adverse event has been reported by the vaccinee, they will be asked to provide further details via a questionnaire completed via an online portal. All data will be securely stored on the Drug Safety Research Unit (DSRU) database. The study population will comprise at least 10,000 adults and children vaccinated with COVID-19 vaccine AstraZeneca (AZD-1222) launched during the mass vaccination programme in the UK.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/02/2021

Actual: 16/02/2021

Study start date

Planned: 01/03/2021

Actual: 01/03/2021

Data analysis start date

Planned: 30/03/2021

Actual: 30/03/2021

Date of interim report, if expected

Planned: 30/09/2021

Actual: 24/09/2021

Date of final study report

Planned: 30/01/2024

Actual: 22/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca UK Ltd

Study protocol

COVID vaccine AZD-1222 protocol v1.7_31_10_22_Abstract.pdf(97.95 KB)

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)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Non-interventional post-authorisation active surveillance study to monitor the utilisation and safety of COVID-19 vaccine AstraZeneca (AZD1222) in the UK.

Main study objective:

To monitor the safety and utilisation of the COVID-19 Vaccine AstraZeneca (AZD-1222) administered to vaccinees under real-world use in the UK

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Active surveillance of safety

Study drug and medical condition

Name of medicine, other

COVID-19 vaccine AstraZeneca (AZD-1222)

Study drug International non-proprietary name (INN) or common name

COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)

Population studied

Short description of the study population

Adults and children vaccinated with COVID-19 vaccine AstraZeneca (AZD1222) launched during the mass vaccination programme in the UK.

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

Pregnant women

Estimated number of subjects

18000

Study design details

Setting

Vaccination sites including large vaccination hubs, GP practices, health clinics etc. in the UK were invited to participate. Vaccinees and/or their representatives (parent/guardian) were provided with study information explaining the surveillance by immunisation staff after vaccination. Sites were provided with supporting information. At least 10,000 adults and children vaccinated with COVID-19 vaccine AstraZeneca (AZD1222) would be recruited.

Comparators

none

Outcomes

• To examine the safety of COVID-19 vaccine AstraZeneca (AZD-1222) through active surveillance of all vaccinee reported adverse events and assessment of incidence. Description of: (i) serious adverse events following vaccination. (ii) adverse events of special interest (AESI) including AESI relevant to vaccinations in general and AESI for AZD-1222. (iii) utilisation of AZD-1222 in the cohort, including vaccination site, demographics of vaccinee and vaccine brand/batch. (iv) use and safety in pregnant, breastfeeding and immunodeficient vaccinees.

Data analysis plan

Monthly summary reports will be produced. Interim reports will be produced at months 1 (or at the first 1,000 vaccinees, whichever comes first), 3 (or at the first 5,000 vaccinees), 6 (or at the first 10,000 vaccinees), 12, 18 and 24. Findings will also be summarised in a final report. Summary descriptive statistics including age, gender and specific co-morbidities/conditions (e.g. sub-populations of interest) reported on questionnaires will be presented, alongside event frequencies. Observed vs expected analysis will be performed for selected AESIs (where appropriate background rate information is available) at

regular intervals throughout the study. For the final report, cumulative incidence risk and rates will be calculated with 95% confidence intervals. Time to onset analyses will be performed for AESI and serious adverse events where a sufficient number of events are reported. Descriptive statistics will be used for other outcome measures.

Summary results

The first participant consented was 1st March 2021. Recruitment ended on the 31st August 2021.

The majority of participants were female (n=10845; 60.4%) and the median (interquartile range [IQR]) age was 50 (43, 62) years. Most participants were from White ethnic groups (English, Welsh, Scottish, Northern Irish, or British) (n=13112; 73.1%).

For participants who reported adverse events, data were censored at two time points; time of receipt of the first non-AstraZeneca COVID-19 vaccine dose (Analysis Group 1) and time at which complete case level data was included for Analysis Group 1 (Analysis Group 2). The non-censored whole cohort data formed Analysis Group 3. Results for Analysis Group 2 were consistent with Analysis Group 1 with less than 20 additional adverse events to Analysis Group 1 being identified and therefore are not presented separately.

Analysis Group 1 contained 19824 events (6591 participants); 399 events were serious (220 participants), 287 were adverse events of special interest (AESIs) (184 participants). Analysis Group 3 contained 22529 adverse events (6582 participants); 507 adverse events were serious (275 participants), 388 were AESIs (251 participants). In both analysis groups headache and fatigue had the highest cumulative risk and rate. The most frequently reported AESI in both analysis groups was anosmia and/or ageusia. Following stratification by age and gender an increased Observed vs Expected (O:E) ratio was seen for anosmia and/or ageusia (both analysis groups) and for anaphylaxis (Analysis Group 3 only).

Data was obtained for special populations; 49 pregnancies were reported in 48 female participants, the outcome of pregnancy included spontaneous abortion (n=6) and four serious adverse events reported in the offspring were considered to be related to at least one dose of the AstraZeneca COVID-19 vaccine.
During the study 11 deaths were reported, including 2 reports of multi organ failure and 2 reports of COVID-19 -related death.

Documents

Study report

COVID vaccine AZD-1222 Final report Abstract_v0.2.pdf(55.5 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)

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