A Phase IV Non-Interventional Enhanced Active Surveillance Study of Adults Vaccinated with AZD1222

First published: 31/05/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS41335

Study ID

46864

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] Sweden

Study description

* The AZ:CONNECTEU study will be stopped. Ongoing participants will be informed and off-boarded. Vaxzevria’s safety continues to be monitored through the implementation of other studies and through established safety reporting platforms across Europe. This is a Phase IV real-world, observational, non-interventional, prospective cohort study of adults vaccinated with AZD1222. The purpose of this study is to assess the safety and tolerability of AZD1222 among AZD1222 vaccinated adults in the real-world setting. The study will use an innovative digital platform (study app and web portal) as well as a traditional call centre to collect participant responses to a series of health and well-being questionnaires over an 18-month period (follow-up after both first and second AZD1222 vaccine doses). Investigators and study personnel will have real-time access to enrolment trends and reported adverse events (AEs) via an investigator dashboard within the digital platform. Research coordinators at vaccination sites will invite AZD1222 vaccinated adults to join the study. Participants can enrol at the vaccination site with assistance from a research coordinator or can take home the study information brochure and enrol within 28 days after the first dose of AZD1222. Participants will receive periodic reminders (either push notifications/e-mails or phone calls) to complete the questionnaires and the participants will also be able to input information into the questionnaires at any time throughout the study period.

Study status

Finalised

Research institutions and networks

Institutions

Parexel International

United States

First published: 19/10/2010

Last updated: 10/12/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Centre Hospitalier D'Argenteuil - Hopital Victor Dupouy Argenteuil, France, Centre Hospitalier Universitaire (CHU) Amiens-Picardie Amiens, France, Medizentrum Essen Borbeck Essen, Germany, Complejo Hospitalario Universitario de Santiago Santiago de Compostela, Spain, H. de San Pedro Logroño, Spain, EAP Mataró 6 (Gatassa) CAP II El Maresme Mataró, Spain, Centro de Salud Monforte de Lemos Monforte de Lemos, Spain

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Brown

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/02/2021

Actual: 04/02/2021

Study start date

Planned: 08/06/2021

Actual: 31/05/2021

Data analysis start date

Planned: 08/07/2021

Actual: 30/06/2021

Date of interim report, if expected

Actual: 15/09/2021

Date of final study report

Planned: 25/02/2022

Actual: 07/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca AB

Study protocol

D8111R00003-PASS-Protocol Final to Client 22 Apr 2021 - Redacted.pdf(845.77 KB)

D8111r00003-PASS-Protocol V2 Final to Client 26 May 2021_Redacted.pdf(3.17 MB)

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

D8111R00003

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of the study is to estimate the incidence of serious adverse events (SAEs), adverse events of special interest (AESIs), and medically-attended adverse events following immunisation (AEFIs) after at least one intramuscular (IM) dose of AZD1222 for 3 months after vaccination.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

COVID-19 immunisation

Population studied

Short description of the study population

Participants are eligible to be included in the study only if all the following criteria apply:

- Aged 18 or older at the time of vaccination.
- Received AZD1222 as the first dose of COVID-19 vaccination in the prior 28 days.
- The participant has provided sufficient details to validate the vaccination (vaccination card, batch/lot number, and/or regional vaccination register details).
- Provided informed consent to participate in the study, either personally or through a legal representative.
- Able and willing to provide responses to study notifications using the mobile device app, web portal, or call centre or have a proxy (a caregiver, family member, or other trusted individual) who can do so on their behalf.
- Able and willing to grant, personally or through a legal representative, permission to contact the participant's healthcare providers and to access the participant's medical records at the time of vaccination and during the post-vaccination follow-up period.

Age groups

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

15000

Study design details

Outcomes

Number of participants with SAEs, AESIs and medically-attended AEFIs with AZD1222 for 3 months after vaccination, -Number of participants with SAEs, AESIs and medically-attended AEFIs with AZD1222 for up to 18 months after vaccination -Number of participants with SAEs, AESIs and medically-attended AEFIs with AZD1222 categorised by age group -Number of participants with select comorbidities with SAEs, AESIs and medically-attended AEFIs with AZD1222 and more (not enough space to fullfil)

Data analysis plan

This study is descriptive in nature. Distribution of participant characteristics at baseline will be described through point estimates (mean, median, rates or proportions) and the corresponding variability (interquartile range, 95% confidence intervals). The primary analysis will only include participants who enrolled within 7 days of vaccination with the first dose of AZD1222. For the primary and secondary analyses, the cumulative incidence of each outcome measure will be computed as the proportion of participants who reported an event among all AZD1222-vaccinated participants who completed each study-defined follow-up interval, as well as among all AZD1222-vaccinated participants regardless of completion status, in combination with corresponding patient-years. Where feasible, incidence rates will be calculated. Subgroup evaluations and sensitivity analyses will also be performed.

Documents

Study results

D8111R00003 EUPAS41335 clinical-study-report Final 20 Apr 2022_Redacted.pdf(1.81 MB)

Study report

d8111r00003-eu-pass-ia2-report_sponsor review_final redacted_17-JAN-2022.pdf(4.54 MB)

D8111R00003-report-1st-ia Final to Client 01 Oct 2021_Redacted.pdf(728.46 KB)

Study, other information

D8111R00003-report-1st-ia Final to Client 01 Oct 2021_Redacted.pdf(728.46 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, Vaccination card/record, Study app, web portal, and call centre, participant emergency contacts and proxies, Medical records (paper or electronic), published studies or other publicly available sources such as registry databases.

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