A Phase IV Open-Label, Non-Randomized, Multi-Cohort, Multicenter Study in Previously Unvaccinated Immunocompromised Adults to Determine the Immunogenicity and Safety of AZD1222 Vaccine for the Prevention of COVID-19. (VICTORIA)

First published: 19/01/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44425

Study ID

50526

DARWIN EU® study

No

Study countries

Thailand

Ukraine

Study description

This was a Phase IV trial and the aim of this study was to learn more about whether AZD1222 can prevent COVID-19 infection in people with a suppressed or compromised (weakened) immune system who had not been previously vaccinated. As a result of increased COVID-19 vaccination rates globally, and particularly in the immunocompromised population, the study could not recruit the required number of unvaccinated/naïve participants. Therefore, the European Medicines Agency removed the requirement for this study and the study was terminated early.

Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

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Institution

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Contact details

Primary lead investigator

R&D BioPharmaceuticals AstraZeneca

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/08/2021

Study start date
Planned: 28/01/2022

Actual: 31/01/2022

Data analysis start date
Planned: 02/06/2023

Actual: 02/06/2023

Date of final study report
Planned: 18/08/2023

Actual: 25/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

EUPAS44425 D8111C00010 - Protocol_18Mar2022_Redacted.pdf (3.01 MB)

D8111C00010-CSP Amendment-3-v4_Redacted_PDFA.pdf (1.43 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/005675/MEA/009

Other study registration identification numbers and links

D8111C00010

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Other

If ‘other’, further details on the scope of the study

The aim of this study is to assess the immunogenicity and safety of AZD1222 for prevention of COVID-19 in immunocompromised adults.

Main study objective:
The purpose of this study is to demonstrate the immunogenicity and safety of AZD1222, AstraZeneca’s approved ChAdOx1 vector vaccine against SARS-CoV-2, in SARS-CoV-2 seronegative immunocompromised individuals who are unvaccinated.

Study Design

Clinical trial phase
Therapeutic use (Phase IV)

Clinical trial randomisation
Non-randomised clinical trial

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J07BX03) covid-19 vaccines
covid-19 vaccines

Medical condition to be studied
COVID-19 immunisation
COVID-19

Population studied

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

Estimated number of subjects

34

Study design details

Outcomes

1. SARS-CoV-2 specific titres in SARS-CoV-2 naïve immunocompromised adults and immunocompetent adults ≥ 18 years Time Frame: 28 days after dosing 2. Seroresponse of SARS-CoV-2 specific titres (≥ 4-fold rise in titres from baseline) in SARS-CoV-2 naïve immunocompromised adults and immunocompetent adults ≥ 18 years Time Frame: 28 days after dosing , 1) Reactogenicity: Incidence of local and systemic solicited AEs for 7 days after each dose of AZD1222 by eDiary. 2) Incidence of unsolicited AEs for 28 days post dose after each vaccination. 3) Incidence of SAEs, MAAEs and AESIs from Day 1 post treatment to Day 365. 4) Absolute and change from baseline for safety lab measures.

Data analysis plan

There was no formal statistical hypothesis testing planned for this study. All analyses – safety and immunogenicity – were descriptive. As the study was

terminated prematurely due to recruitment challenges, analyses were streamlined, and no summaries were produced by individual immunocompromised cohort. No comparisons were done between the immunocompromised and immunocompetent cohorts. Antibody titers (pseudoneutralizing and anti-spike) were summarized as geometric mean titers with 95% confidence intervals based on the lognormal distribution. Seroresponse (4-fold increase in titers compared to baseline) was reported as percentage and 95% exact Clopper-Pearson confidence intervals. The primary analysis timepoint was 28 days post dose 2, a secondary analysis timepoint summarized post dose 3 antibody titers. Exploratory endpoints of nucleocapsid antibodies and anti-vector antibodies were performed similarly to primary and secondary immunogenicity analyses.

Documents

Study results

D8111C00010-CSR synopsis_Redacted_PDFA.pdf (1.48 MB)

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