

# COV-COMPARE: A study to compare the VLA2001 and AZD1222 vaccines against COVID-19 in adults

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| <b>Submission date</b><br>26/04/2021   | <b>Recruitment status</b><br>No longer recruiting        | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>27/04/2021 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                            |
| <b>Last Edited</b><br>07/06/2021       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan           |
|  |  | <input type="checkbox"/> Results                             |
|  |  | <input type="checkbox"/> Individual participant data         |
|  |  | <input type="checkbox"/> Record updated in last year         |

## Plain English summary of protocol

### Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

Valneva's COVID-19 vaccine candidate is called VLA2001. The aim of this study is to compare the immune response to the VLA2001 vaccine to the AZD1222 vaccine in adults aged 30 and older, and to evaluate the safety and tolerability of VLA2001 in adults aged 18 and older.

### Who can participate?

Adults aged 18 and older who have not received any COVID-19 vaccination yet, regardless of whether they had been infected by SARS-CoV-2 before or not. Please visit <https://www.ukcovid19study.com> for more information.

### What does the study involve?

Participants are randomly allocated to receive either the VLA2001 or AZD1222 vaccine. The participants and treating doctors will not know which of the two vaccines will have been given. The aim is to compare the immune response and safety of the two vaccines, and to establish a robust safety database for VLA2001. Participants will receive VLA2001 at the dose selected based on the results of the first study. The vaccination schedule will be aligned between the two vaccines, i.e. vaccinations will occur on Days 1 and 29, and follow-up visits will be conducted for 1 year.

### What are the possible benefits and risks of participating?

This is the second study in human participants and the clinical benefits of VLA2001 have not yet been established. Although the vaccine might induce immune responses that may be protective, participants might not experience any direct benefit from taking part in this study. The information obtained from this study may help prevent future participants from contracting

COVID-19 and will provide important information about how well people respond to VLA2001. There may be risks to being in this study from the study vaccine or from some of the procedures or tests carried out in this study.

Where is the study run from?  
Valneva (Austria)

When is the study starting and how long is it expected to run for?  
July 2020 to June 2022

Who is funding the study?  
Department of Health and Social Care (UK)

Who is the main contact?  
Christian Taucher  
VLA2001-301@valneva.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Christian Taucher

**Contact details**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2021-000522-97

**Integrated Research Application System (IRAS)**  
294164

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
VLA2001-301, IRAS 294164

## Study information

**Scientific Title**

A randomized, observer-blind, controlled, superiority study to compare the immunogenicity against COVID-19 of the VLA2001 vaccine and the AZD1222 vaccine in adults

## **Acronym**

COV-COMPARE

## **Study objectives**

The purpose of this study is to compare the immunogenicity of the VLA2001 vaccine to the AZD1222 vaccine in adults aged 30 years and older; and to evaluate the safety and tolerability of VLA2001 in adults aged 18 years and older.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 20/04/2021, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8221, +44 (0) 207 104 8063; gmsouth.rec@hra.nhs.uk), REC ref: 21/NW/0125

## **Study design**

Randomized observer-blind controlled superiority Phase III study

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

COVID-19 (SARS-CoV-2 infection)

## **Interventions**

About 3000 participants aged 30 years and above will be randomized via an Interactive Response System (IRS) in a 2:1 ratio to receive two intramuscular recommended doses of either VLA2001 (n=2000) or AZD1222 (n=1000). In addition, approximately 1000 subjects aged 18-29 years will participate in this study in a non-randomized, open-label fashion to receive VLA2001. The two doses of vaccination for both vaccines will be administered 28 days apart on Days 1 and 29.

Participants will be followed up in the study for approximately 11 months after their second vaccination.

## **Intervention Type**

Biological/Vaccine

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

VLA2001, AZD1222

## **Primary outcome(s)**

#### Immunogenicity:

1. Immune response after completion of a two-dose immunization schedule, as determined by the geometric mean titer (GMT) of SARS-CoV-2-specific neutralizing antibodies measured using a neutralization assay on Day 43

#### Safety:

2. Frequency and severity of any Adverse Events (AE) collected during study visits up to Day 43 post-vaccination

#### Key secondary outcome(s)

##### Immunogenicity:

1. Proportion of participants with seroconversion measured using a neutralization assay on Day 8 (age 55+ only), Day 29, Day 43, Day 71, Day 208 and Day 365
2. Immune response, as determined by the GMT of SARS-CoV-2-specific neutralizing antibodies measured using a neutralization assay on Day 8 (age 55+ only), Day 29, Day 71, Day 208 and Day 365
3. Immune response, as determined by the GMT of IgG antibodies to SARS-CoV-2 S-protein measured using an Enzyme-Linked Immunosorbent Assay (ELISA) on Day 8 (age 55+ only), Day 29, Day 43, Day 71, Day 208 and Day 365
4. T-cell responses assessed using T-spot assay and/or intracellular cytokine staining at selected timepoints (yet to be defined) in a subset of participants

##### Safety:

5. Frequency and severity of solicited injection site and systemic reactions captured using electronic diaries within 7 days after each and after any vaccination
6. Frequency and severity of any AE collected during study visits during the entire study period
7. Frequency and severity of any unsolicited AE collected during study visits until Day 43
8. Frequency and severity of any unsolicited vaccine-related AE collected during study visits until Day 43
9. Frequency and severity of any serious adverse event (SAE) collected during study visits during the entire study period
10. Frequency and severity of any adverse event of special interest (AESI) collected during study visits during the entire study period

#### Completion date

30/06/2022

## Eligibility

#### Key inclusion criteria

1. Participants must have read, understood, and signed the informed consent form (ICF)
2. Participants of either gender aged 18 years and older at screening
3. Medically stable
4. Must be able to attend all visits of the study and comply with all study procedures
5. Women of childbearing potential (WOCBPs) must be able and willing to use at least one highly effective method of contraception for a minimum of 3 months after the last dose of study vaccine
6. WOCBPs must have a negative pregnancy test prior to each vaccination

#### Participant type(s)

Healthy volunteer

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Key exclusion criteria

1. Participant is pregnant or planning to become pregnant within 3 months after study vaccine administration
2. History of allergy to any component of the vaccine
3. Significant infection (e.g. positive SARS-CoV-2 RT-PCR) or other acute illness, including fever >100 °F (>37.8 °C) 48 hours before vaccination
4. Participant has a known or suspected defect of the immune system
5. Participant has a history of cerebral venous sinus thrombosis, heparin-induced thrombocytopenia or antiphospholipid syndrome
6. Participant has a history of malignancy in the past 5 years other than squamous cell or basal cell skin cancer. If there has been surgical excision or treatment more than 5 years ago that is considered to have achieved a cure, the participant may be enrolled. A history of hematologic malignancy is a permanent exclusion. Participants with a history of skin cancer must not be vaccinated at the previous tumour site
7. History of drug dependency or current use of drug abuse or alcohol abuse at screening
8. Significant blood loss (> 450 ml) or has donated one or more units of blood or plasma within 6 weeks prior to the expected day of randomization (Visit 1)
9. History of clinically significant bleeding disorder, or prior history of significant bleeding or bruising following IM injections or venepuncture
10. Severe and uncontrolled ongoing autoimmune or inflammatory disease History of Guillain-Barre syndrome or any other demyelinating condition
11. Any other significant disease, disorder or finding which in the opinion of the investigator may significantly increase the risk to the volunteer

## Prior/concomitant therapy:

12. Receipt of immunoglobulin or another blood product within the 3 months before expected day of randomization (visit 1) in this study or those who expect to receive immunoglobulin or another blood product during this study
13. Receipt of medications and or vaccinations intended to prevent COVID-19
14. Receipt of any vaccine (licensed or investigational), other than licensed influenza vaccine, within 28 days prior to the expected day of randomization (Visit 1)

## Others:

15. Any member of the study team or sponsor
16. An immediate family member or household member of the study's personnel

## Date of first enrolment

28/04/2021

**Date of final enrolment**

03/06/2021

**Locations****Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre****University Hospitals Bristol and Weston NHS Foundation Trust**

Clinical Research Facility

60 St Michaels Hill

Bristol

United Kingdom

BS2 8DX

**Study participating centre****University Hospitals Birmingham NHS Foundation Trust**

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2WB

**Study participating centre****The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital Newcastle

Level 6, Leazes Wing

Royal Victoria Infirmary

Queen Victoria Road

Newcastle

United Kingdom

NE1 4LP

**Study participating centre****Southampton University Hospitals NHS Trust**

Tremona Road

Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**

**University Hospital Plymouth NHS Trust**

1 Roscoff Rise  
Derriford  
Level 2  
MSCP  
Bircham Park Offices  
Plymouth  
United Kingdom  
PL6 5FP

**Study participating centre**

**St George's University Hospitals NHS Foundation Trust**

Room 0.160, Level 0  
Jenner Wing, St George's  
Cranmer Terrace  
London  
United Kingdom  
SW17 0RE

**Study participating centre**

**Chelsea and Westminster Hospital NHS Trust**

369 Fulham Road  
Chelsea  
London  
United Kingdom  
SW10 9NH

**Study participating centre**

**NIHR UCLH Clinical Research Facility**

4th Floor  
170 Tottenham Court Road  
London  
United Kingdom  
W1T 7HA

**Study participating centre**

**Royal Free London NHS Foundation Trust**

Pond St  
London  
United Kingdom  
NW3 2QG

**Study participating centre**

**Cambridge Biomedical Research Centre**

Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**

**University Hospitals Coventry & Warwickshire**

Clifford Bridge Road  
Walsgrave  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**

**Lakeside Healthcare Research**

2nd Floor Urgent Care (UC) Building  
Cottingham Road  
Corby  
Northampton  
United Kingdom  
NN17 2UR

**Study participating centre**

**Nottingham University Hospitals NHS Trust**

B Floor, Medical School  
Queen's Medical Centre Campus  
Derby Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**



**NHS Foundation Trust Royal Liverpool University Hospital**

2nd Floor  
Prescott Street  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**

**Northern Care Alliance NHS Group, Salford Royal NHS Foundation Trust**

Stott Lane  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**

**Barnsley Hospital NHS Foundation Trust**

Lock 14  
Gawber Road  
Barnsley  
United Kingdom  
S75 2EP

**Study participating centre**

**Blackpool Teaching Hospitals NHS Foundation Trust**

Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR

**Study participating centre**

**Northumbria Healthcare NHS Foundation Trust**

North Tyneside General Hospital  
Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

**Study participating centre**

**Queen Elizabeth University Hospital**

Glasgow Clinical Research Facility  
5th Floor

1345 Govan Road  
Glasgow  
United Kingdom  
G51 4TF

**Study participating centre**

**Panthera London**  
Enfield 1 Woodall Road  
London  
United Kingdom  
EN3 4GS

**Study participating centre**

**Panthera Biopartners Manchester**  
610 Bury Rd  
Rochdale  
United Kingdom  
OL11 4AU

**Study participating centre**

**Panthera Biopartners Preston**  
73 St Gregory Road  
Preston  
United Kingdom  
PR1 6YA

**Study participating centre**

**Royal Surrey County Hospital NHS Foundation Trust**  
Egerton Road  
Guildford  
United Kingdom  
GU2 7XX

**Study participating centre**

**Cheadle Community Hospital**  
Research Unit  
Ward 3  
Royal Walk  
Cheadle  
United Kingdom  
ST10 1NS

**Study participating centre**  
**Western General Hospital, Edinburgh – NHS Lothian**  
Crewe Rd S  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**  
**North Bristol NHS Trust**  
Southmead Rd  
Bristol  
United Kingdom  
BS10 5NB

## **Sponsor information**

**Organisation**  
Valneva (Austria)

**ROR**  
<https://ror.org/03xk4a758>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Department of Health and Social Care

**Alternative Name(s)**  
Department of Health & Social Care, DH

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data-sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |