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

Submission date
26/04/2021

Recruitment status
No longer recruiting

Registration date
27/04/2021

Overall study status
Completed

Last Edited
07/06/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Study website
https://www.ukcovid19study.com

Contact information

Type(s)
Scientific

Contact name
Mr Christian Taucher

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Additional identifiers

EudraCT/CTIS number
2021-000522-97

IRAS number
294164

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Available at https://www.ukcovid19study.com

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 measure
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

Secondary outcome measures
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

Overall study start date
20/07/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4000

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
England

Scotland

United Kingdom

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
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B15 2WB

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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Royal Victoria Infirmary
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre

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Study participating centre
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Sponsor information

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Industry

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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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2023

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