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Post-approval follow-up study for the COV001 and COV002 trials to determine the long-term safety and character of immune response to the Oxford-AstraZeneca coronavirus vaccine

Submission date
31/08/2021

Recruitment status
No longer recruiting

Registration date
01/09/2021

Overall study status
Completed

Last Edited
07/08/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] 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.
On the 29th December 2020 the UK regulator MHRA authorised the Oxford/AstraZeneca ChAdOx1 nCOV-19 vaccine for emergency use. The first participant received ChAdOx1 nCoV-19 on 23rd April 2020, so there is limited long-term data following human exposure to this new vaccine. Since 2012, several hundred patients have received different ChAdOx-based vaccines to prevent other diseases, including influenza, tuberculosis, prostate cancer and malaria, where to date, no serious adverse events were considered related to those vaccines. Under the "conditions of authorisation for emergency supply" in the UK and other territories, AstraZeneca agreed to meet the demands of a pharmacovigilance risk management plan to provide ongoing monitoring of individuals who have received the vaccine.
This safety and immunogenicity extension study aims partly to fulfil those obligations, while also gathering data to permit investigation into the character and persistence of the immune responses that have been stimulated. As such, this is an observational study, where the researchers do not propose to administer additional medicines. The risk to participants is limited to those resulting from simple blood tests at the two study visits. The findings that result from COV009 will be valuable to vaccine developers and policymakers to inform decisions on future vaccine scheduling and design.

Who can participate?
Participants previously enrolled in the UK Phase I/II (COV001) and Phase II/III (COV002) trials

What does the study involve?
Participants will be assessed at two study visits at 6 and 12 months. Each study visit will consist of a blood draw and collection of information on new adverse events since enrolment.

What are the possible benefits and risks of participating in the study?
The participants will have the opportunity to help clinicians better understand the long-term safety of the Oxford/AstraZeneca vaccine. The risks are limited to localised bruising and discomfort can occur at the site of blood sampling. Infrequently fainting may occur. The majority of the blood draws are small volumes.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
August 2021 to December 2024

Who is funding the study?
AstraZeneca (UK)

Who is the main contact?
Nelly Owino, nelly.owino@paediatrics.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Andrew Pollard

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2021-003382-36

IRAS number
300456

ClinicalTrials.gov number
NCT04324606

Secondary identifying numbers
OVG2021/03, IRAS 300456, CPMS 50168

Study information

Scientific Title
Safety and immunogenicity extension study for ChAdOx1 nCoV-19

Acronym
COV009

Study objectives
This study aims to:
1. Document the long-term safety profile of the ChAdOx1 nCoV-19 vaccine
2. Evaluate the character and durability of immune responses that are stimulated by the ChAdOx1 nCoV-19 vaccine

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/08/2021, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8372; berkshire.rec@hra.nhs.uk), REC ref: 21/SC/0261

Study design
Multi-centre prospective safety study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The study aims to enrol participants in parallel with the final visit of their parent trial (COV001 /002), provided they have consented to be contacted for future research.
At consent, participants will have sufficient opportunity to read and understand the contents of the patient information sheet prior to being invited to give informed written consent, with further opportunities to ask questions and seek clarification at the consent and enrolment visit. Participants will be consented to allow the central study team to access their NHS SARS-CoV-2 nucleic acid amplification test (NAAT) results including viral sequencing where it is available from NHS digital and local sequencing labs, using the participants NHS number or other personal identifiers in the event of a diagnosis of COVID-19 during the study period. Consent will also be sought to access all participant's COVID-19 vaccination records through NHS digital or by accessing medical records.

The following data will be collected for any participant that has completed the final study visit for the parent trial on a different day to enrolment in COV009. Any new:
1. COVID-19 diagnoses
2. Serious adverse events (SAEs)
3. Adverse events of special interest (AESI)
4. Administration of any vaccines
5. Participation in other clinical trials

Participants will be assessed at two study visits after consent and enrolment:
1. At 6 months (study visit 1 – SV1)
2. At 12 months (study visit 2 – SV2)

Each study visit will consist of a blood draw for immunology and questions to capture details of any of the following new events since enrolment:
1. COVID-19 diagnoses
2. Serious adverse events (SAEs) – the participant may also be asked about any new medical diagnoses or medically attended adverse events to ensure any SAEs are not missed
3. Adverse events of special interest (AESI)
4. Administration of any vaccines (any vaccine including but not limited to COVID vaccines are permissible but must be recorded in the eCRF)
5. Participation in other clinical trials

In the event that a participant is unable to attend an in-person clinic visit, telephone safety assessments may be conducted instead. Participants will be able to contact the study team outside of study visits 1 and 2 to report any new relevant medical event as stated in the patient information sheet

Following enrolment, some participants (Oxford and Southampton sites only) will be allocated sequentially at enrolment to the exploratory immunology subgroup.

For most participants up to 10 ml of blood will be taken at each of the two visits, totalling 20 ml for the study. For those participants allocated to the 'exploratory immunology' subgroup, a larger volume of blood, up to 50 ml at each visit, will be taken.

Each participant may exercise his or her right to withdraw from the study at any time. In addition, the investigator may terminate a participant's involvement in the study, at any time, if the investigator considers it necessary.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Long-term safety of the ChAdOx1 nCoV-19 vaccine measured from the registry of serious adverse events (SAEs) and adverse events of special interest (AESIs) at visit 1 (6 months, +/- 28 days) and visit 2 (12 months, +/- 28 days) and may also be reported by the participant at other times during the study

Secondary outcome measures
Character and durability of the immune response to vaccination measured by the immune responses (for a subset of participants, in exploratory immunology group), anti-SARS-CoV-2 spike protein immunoglobulins, and neutralising antibodies against SARS-CoV-2 at visit 1 (6 months +/- 28 days) and visit 2 (12 months +/-28 days)

Overall study start date
20/08/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Participated in the COV001 - Phase I/II or COV002 - Phase II/III trials
2. Able and willing to provide written, informed consent to participate in the study
3. Able and willing (in the investigator's opinion), to comply with all study requirements
4. Consent to general practitioner or responsible physician being notified of participation in the

study
5. Consent to allow investigators to discuss their medical information with their general practitioner (GP) or responsible physician, and to access any medical records where relevant to the study
6. Consent to access NHS SARS-CoV-2 NAAT results, including viral sequencing, results from NHS Digital and local sequencing labs, as well as COVID-19 vaccination records if available

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
Up to 12,000 participants from the COV001 and COV002 trials

Total final enrolment
1077

Key exclusion criteria
1. Participants who have enrolled on a clinical trial of an investigational medicinal product (CTIMP) for a novel COVID-19 vaccine will be excluded. Examples would include the COV-Variant or ComCOV trials
2. Participants who fail to enrol onto COV009 within 26 weeks of their last study visit on the parent study will be excluded. If consent is not obtained within 26 days from the last visit on the parent trial, the participant will become ineligible for COV009

Date of first enrolment
01/09/2021

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre

Churchill Hospital
Oxford University, Oxford Vaccine Group
CCVTM
Oxford
United Kingdom
OX3 7LE

Study participating centre
University Hospital of Southampton
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
St Mary's Hospital
The Bays
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W2 1BL

Study participating centre
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Queen Elizabeth Hospital
Mindelsohn Way
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United Kingdom
B15 2GW

Study participating centre
St Georges University Hospital
St Georges Hospital
Blackshaw Road
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London
United Kingdom
SW17 0QT

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
St Cadoc's Hospital .
Lodge Road
Caerleon
Newport Gwent
United Kingdom
NP18 3XQ

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Southmead Hospital
Southmead Road
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BS10 5NB

Study participating centre
University Hospitals Bristol
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Queens Medical Centre
Derby Road

Nottingham
United Kingdom
NG7 2UH

Study participating centre
Garthnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
Freeman Hospital
High Heaton
Newcastle Upon Tyne
United Kingdom
NW12PG

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Cambridge Clinical Research Facility
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
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Waverleygate
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EH1 3EG

Study participating centre
St Thomas Hospital
Department of Infection
Westminster Bridge Road
London
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SE1 7EH

Study participating centre
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SW17 0RE

Study participating centre
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

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

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Summary data only will be published. No identifiable personal data will be used.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.1	24/08/2021	31/08/2021	No	No

Protocol file	version 3.0	28/10/2021	29/11/2021	No	No
Participant information sheet	version 4.0	18/07/2022	19/08/2022	No	Yes
Protocol file	version 4.0	18/07/2022	19/08/2022	No	No
HRA research summary			26/07/2023	No	No
Protocol file	version 4.1	18/07/2024	07/08/2024	No	No