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A study of a new vaccine against the MERS virus in adults aged 50 to 70 years

Submission date 18/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/04/2023	**Overall study status** Ongoing	
Last Edited 28/07/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
This is a trial of a new vaccine against Middle East Respiratory Syndrome (MERS) in volunteers aged 50 to 70 years old.
MERS has been identified as one of the most worrying outbreak diseases. It is a viral respiratory illness that can cause severe pneumonia and even death. The MERS virus was identified in 2012 in Saudi Arabia. 2,300 cases and over 800 deaths have occurred so far. It continues to cause a small number of cases each year in Saudi Arabia. Currently, there is no treatment for MERS and no approved vaccine.
This study is of a vaccine against MERS, called ChAdOx1 MERS, which has been developed by The University of Oxford. The vaccine is very similar to the Oxford/AstraZeneca COVID-19 vaccine and is made using the same technology. Researchers have already completed two small clinical trials using ChAdOx1 MERS in healthy adults aged 18 to 50 years.
The purpose of this new study is to:
1. Assess the safety and the immune response to the MERS vaccine in older adults
2. Investigate whether having previously received doses of the Oxford/AstraZeneca COVID-19 vaccine affects the immune response to the MERS vaccine.

Who can participate?
Healthy volunteers aged 50 to 70 years, half of whom will have previously been vaccinated with at least two doses of the Oxford/AstraZeneca COVID-19 vaccine

What does the study involve?
Participants will be screened for eligibility with an initial online questionnaire followed by a phone call and an in-person medical assessment. Eligible participants will be invited to attend the first vaccination visit when they will be assigned at random to get two doses (given 12 weeks apart) of either the study vaccine or a ‘placebo’ injection (sterile salt water). For every six participants recruited, five will receive the trial vaccine and one will receive the placebo. Neither the participants nor the study team (who assess outcomes) will know if the vaccine or placebo was given until the end of the study. Participants will be followed up for 1 year to monitor their safety and immune responses.

What are the possible benefits and risks of participating?
Participants will not benefit directly as they are highly unlikely to be at direct risk of MERS infection currently. Participants will be informed that they should not anticipate any protection from potential future MERS infection by participating in this study.
There is no risk of contracting MERS from the vaccine, and the participants will not be exposed to the MERS virus at any point during this study. We can predict from past experience with other ChAdOx1 vaccines what the symptoms should be like with this new vaccine. However, this vaccine is in an early stage of development and had only been tested in 53 people so far. Therefore, there is a chance the participants could experience an unexpectedly severe side effect or a new side effect that has not been seen before.
As with any vaccine, the participants may experience some discomfort at the injection site. Usually this is mild but sometimes individuals experience more significant pain which might interfere with their usual activities. Post-vaccination arm pain usually resolves within a few days but may occasionally persist for up to a week or longer. Other less common symptoms around the injection site might include redness, swelling, itchiness or a feeling of warmth. During the first 24-48 hours after vaccination the participants may experience flu-like symptoms (muscle aches, joint aches, feverishness, chills, headache, nausea, tiredness and/or feeling generally unwell), which are expected to resolve within a few days.
Vaccine reaction symptoms were measured in the large ChAdOx1 COVID-19 vaccine trials involving over 10,000 volunteers. Symptoms were mostly described as mild, although a minority described temporary moderate or severe-intensity symptoms. The dose given was equivalent to the dose in this trial. Individuals tend to have fewer and milder symptoms after their second dose.
The following items have been listed as extremely rare serious reactions following the ChAdOx1 COVID-19 vaccine: serious rare blood clot disorders, Guillain-Barré syndrome (rare neurological illness), inflammation of the spinal cord, anaphylaxis/serious allergic reactions, capillary leak syndrome, risk of bleeding with intramuscular administration. It is currently unknown whether these rare reactions may occur with other ChAdOx1 vaccines but investigators using ChAdOx1 MERS should be alert to them.
With any new medicine or vaccine that is in early development there is always a possibility of an unpredicted or unexpected side effect occurring. If the participants experience concerning or unexpected symptoms, they should seek urgent medical advice or phone the 24hr study contact number and speak to a study doctor.
When people are vaccinated with ChAdOx1 MERS they should make the intended immune response against the MERS spike protein. However, they may also make an immune response against ChAdOx1 itself. This theoretical risk could mean that the ChAdOx1 MERS vaccine in this trial might block future doses of ChAdOx1-based (or other adenovirus-based) vaccines from working well. We aren't certain whether this effect truly occurs and this is one of the questions that this study will look at.
Before each vaccination, the ongoing eligibility of the volunteer will be reviewed. ChAdOx1 MERS will be administered intramuscularly according to vaccine administration SOPs. The injection site will be covered with a sterile dressing and the volunteer will stay at the trial site for observation, in case of immediate adverse events. After 30 min the sterile dressing will be removed, the injection site inspected and vital signs checked.
An oral thermometer, tape measure and electronic diary access will be given to each volunteer, with instructions on use, along with a contact card including the emergency 24-hour telephone number to contact the on-call study physician if needed.
Blood sampling may cause slight pain and occasionally bruising. Occasionally, people feel light-headed, nauseous or faint. The amounts of blood taken are fairly small and should be well tolerated by healthy adults. Stool sample collection is opt-in only and is a straightforward procedure.
As we carry out medical tests throughout the trial it is possible that we pick up previously

unknown health issues. If abnormal results or undiagnosed conditions are found during the study, these would be discussed with the participants and, if they agree, their GP would be informed. The GP might carry out further investigations (blood tests, scans or referral to specialists).
The possible adverse effects of the ChAdOX MERS vaccine on the outcome of pregnancy are unknown and pregnant women will be excluded from the study. Women of childbearing potential will be required to use an effective contraceptive measure during the study. If a volunteer becomes pregnant during the trial, she will be followed up for clinical safety assessment until the pregnancy outcome is determined with her ongoing consent. The baby will be followed up for up to 3 months after delivery. Male participants with female partners are not required to use barrier methods for contraception.

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

When is the study starting and how long is it expected to run for?
January 2023 to January 2027

Who is funding the study?
Coalition for Epidemic Preparedness Innovations (Norway)

Who is the main contact?
Bilyana Stoilova, info@ovg.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2022-002159-21

Integrated Research Application System (IRAS)
1006223

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
OVG2022/02, IRAS 1006223, CPMS 55286

Study information

Scientific Title
A Phase I study to determine the safety and immunogenicity of a new vaccine against the Middle East Respiratory Syndrome Coronavirus in Adults aged 50 to 70 years

Acronym
MERS003

Study objectives
Primary objective:
To assess the safety, tolerability and reactogenicity profile of the ChAdOx1 MERS vaccine in adult volunteers aged 50 to 70 years

Secondary objective:
To assess the cellular and humoral immunogenicity of the ChAdOx1 MERS vaccine in adult volunteers aged 50 to 70 years

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 21/04/2023, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol BS1 6PN, UK; +44 (0)207 1048171, +44 (0)207 104 8141, +44 (0)207 104 8272; oxforda.rec@hra.nhs.uk), ref: 23/SC/0047

Study design
Double-blind randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection

Interventions
Participants will be randomized within their group (which is based on past vaccination with ChAdOx1 nCov-19) to receive either ChAdOx1 MERS or saline placebo in a 5:1 ratio.

Arm 1: two doses of ChAdOx1 MERS vaccine 5x10e10 vp
Arm 2: two doses 0.9% saline placebo

Both vaccine and placebo are administered via intramuscular route as two doses given at 0 and 12 weeks.

Follow-up activities: the study consists of a screening visit, two vaccination visits and five follow-up visits (at days 14 and 28 after the fists vaccination and at days 14, 28 and 281 after the second vaccination). During the follow-up visits vital signs (heart rate, temperature, blood pressure) will be taken, except on day 281 post second vaccination. Targeted medical history and physical examination may be performed, if required. Any COVID-19 infections and vaccinations will be recorded. Solicited AEs will be collected in an electronic diary within 7 days of each vaccination. Unsolicited AEs will be collected within 28 days of each vaccination in the electronic diary. A review of ongoing AEs and collection of SAEs and AESI will be performed for the whole duration of the study follow-up period. Blood samples will be collected at each of the follow-up visits. A review of electronic diary entries and laboratory blood tests will be performed at the follow-up study visits.

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
ChAdOx1 MERS vaccine

Primary outcome(s)

1. Occurrence of solicited local reactogenicity signs and symptoms within 7 days of each vaccination, self-reported in the participant's electronic symptom diary
2. Occurrence of solicited systemic reactogenicity signs and symptoms within 7 days of each vaccination, self-reported in the participant's electronic symptom diary
3. Occurrence of unsolicited adverse events (AEs) within 28 days of each vaccination, self-reported in the participant's electronic symptom diary and from clinical evaluation at follow-up visits
4. Change from baseline for safety laboratory measures within 28 days of each vaccination, measured from blood tests taken at each visit
5. SAEs and AESIs for the whole duration of the study follow-up period, self-reported in the participant's electronic symptom diary and from clinical evaluation at follow-up visits

Key secondary outcome(s))
1. MERS spike protein specific serological response measured by ELISA before the first vaccination (day 0), 14 and 28 days after the first vaccination, before the second vaccination (day 84), 14, 28 and 281 days after the second vaccination
2. MERS spike protein T cell response measured by IFN-γ ELISPOT before the first vaccination (day 0), 14 and 28 days after the first vaccination, before the second vaccination (day 84), 14, 28 and 281 days after the second vaccination

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Adults aged between 50 to 70 years (inclusive) at the time of screening
2. Medically stable, such that according to investigator judgement hospitalisation within the study period is not anticipated, and the participant appears likely to be able to remain a study participant through the end of protocol-specified follow-up. Planned elective procedures for pre-existing conditions are allowable. A stable medical condition is defined as disease not requiring significant change in therapy or hospitalisation for worsening disease during the 90 days prior to enrolment.
3. Able to attend the scheduled visits and to comply with all study procedures, including internet access for the recording of diary cards
4. Willing to allow confirmation of their past medical history either through: provision of or access to medical record summary, allowing investigators to obtain a copy of their medical history from their GP practice or accessed via the electronic patient record or other medical documentation provided by the participant
5. Agreement to refrain from blood donation during the course of the study
6. Willing and able to give informed consent for participation in the study
7. For women of childbearing potential only (As defined by protocol section 8.4): Willing to use effective contraception as defined from one month prior to receiving the first vaccine and for the duration of the study AND a negative pregnancy test on the days of screening and vaccination.
8. Willing to provide their national insurance number or passport number to be registered on The Over-Volunteering Prevention System (TOPS)
9. Willing to allow his or her General Practitioner and/or Consultant, if appropriate, to be notified of participation in the study
10. Group 1 specific inclusion criteria: a confirmed history of receiving at least TWO doses of the ChAdOx1 nCov-19 (Oxford/AZ COVID-19) vaccine prior to enrolment

11. Group 2 specific inclusion criteria: no previous history of receiving ANY doses of the ChAdOx1 nCov-19 (Oxford/AZ COVID-19) vaccine prior to enrolment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
70 years

Sex
All

Total final enrolment
84

Key exclusion criteria
1. Participation in another research study involving an investigational product or that which may compromise the integrity of the study (e.g. significant volumes of blood already taken in previous study) in the past 12 weeks, or are planning to do so within the trial period
2. Planned receipt of another adenoviral vectored vaccine (e.g. Oxford/AstraZeneca or Janssen COVID-19 vaccines) within 90 days of any study vaccine.
3. Previous immunisation with an investigational MERS vaccine
4. History of prior confirmed or suspected MERS infection
5. Administration of immunoglobulins and/or any blood products within the three months preceding the planned administration of the vaccine candidate
6. Any confirmed or suspected immunosuppressive or immunodeficient state, including HIV infection; asplenia; severe infections or receipt of immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy within the preceding 12 months or long-term systemic corticosteroid therapy (including for more than 7 days consecutively within the previous 3 months)
7. History of allergic disease or reactions likely to be exacerbated by any component of the vaccine including hypersensitivity to the active substance or to any of the excipients of the IMP or Vaxzevria (i.e. the Oxford/AstraZeneca COVID-19 vaccine)
8. History of allergic reaction to aminoglycoside antibiotics
9. History of hereditary angioedema, acquired angioedema, or idiopathic angioedema
10. History of anaphylaxis in relation to vaccination
11. History of cancer (except basal cell carcinoma of the skin and cervical carcinoma in situ)
12. History of serious psychiatric condition likely to affect participation in the study
13. Female participants who are pregnant, breastfeeding/lactating or planning pregnancy during the course of the study
14. Bleeding disorder (e.g. Factor deficiency, coagulopathy or platelet disorder), or prior history of significant bleeding or bruising following IM injections or venepuncture

15. History of confirmed major thrombotic event (including cerebral venous sinus thrombosis, deep vein thrombosis, pulmonary embolism), history of antiphospholipid syndrome, or history of heparin induced thrombocytopenia
16. Individuals who have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with Vaxzevria (i.e. the Oxford/AstraZeneca COVID-19 vaccine)
17. Individuals who have previously experienced episodes of capillary leak syndrome
18. Severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder, or neurological illness, as judged by the Investigator (note, mild/moderate well-controlled comorbidities are allowed)
19. Suspected or known current alcohol abuse as defined by an alcohol intake of greater than 42 units every week
20. Suspected or known injecting drug abuse in the 5 years preceding enrolment
21. Detectable circulating hepatitis B surface antigen (HBsAg)
22. Seropositive for hepatitis C virus (antibodies to HCV)
23. Any clinically significant finding on screening investigations, that are either unlikely to resolve or do not resolve on repeat testing (at the discretion of an Investigator) within the recruitment timeline of the study
24. Any other significant disease, disorder or finding which may significantly increase the risk to the volunteer because of participation in the study, affect the ability of the volunteer to participate in the study or impair interpretation of the study data

Date of first enrolment
18/04/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Vaccine Group
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Study participating centre
Oxford Vaccine Group
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Coalition for Epidemic Preparedness Innovations

Alternative Name(s)
CEPI Norway, CEPI

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication (further details will be provided later).

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes