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VITAL01: A study of a new vaccine against Lassa fever in adults aged 18-55 years

Submission date
05/03/2025

Recruitment status
Not yet recruiting

Registration date
11/06/2025

Overall study status
Ongoing

Last Edited
11/06/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Lassa fever is a viral disease carried by rodents. Approximately 60 million people in West Africa are at risk of infection each year. While most cases are mild, severe infections can be fatal, especially for pregnant women and their unborn baby. Survivors may experience long-term complications such as hearing loss and balance disorders. With no formal treatment or vaccine available, prevention and vaccine development are critical. The Oxford Vaccine Group are conducting a clinical trial in which ChAdOx1 LassaJ will be given to humans for the first time to assess the safety and tolerability of ChAdOx1 LassaJ in healthy volunteers.

Who can participate?
Volunteers aged between 18 and 55 years old and in good health.

What does the study involve?
Participants will be recruited into one of two groups and receive two doses 12 weeks apart of either the study vaccine or a placebo.

What are the possible benefits and risks of participating?
By participating in this trial, participants will help research into the development of a safe and effective vaccine to protect against the Lassa virus, but they will not directly receive any personal health benefit from the study or its procedures.

The most likely side effects that recipients of ChAdOx1 LassaJ may experience are short-lived local reactions (primarily injection site tenderness or pain) and systemic reactions (fatigue, headache, malaise, feverishness) that resolve completely within days. Very rare serious reactions have been identified as part of post-marketing surveillance of ChAdOx1 nCoV-19 (Oxford /AstraZeneca COVID-19 vaccine). These include thrombosis with thrombocytopenia, immune thrombocytopenic purpura, Guillain-Barré syndrome, transverse myelitis, capillary leak syndrome and anaphylaxis. It is currently unknown whether these very rare reactions occur with other ChAdOx vaccines. As ChAdOx1Lassa is similar to ChAdOx1 nCoV-19, participants will be informed about these conditions as part of the informed consent process for the trial. Investigators will be aware of potential signs of these conditions.
Although estimates remain uncertain, unilateral or bilateral sensorineural hearing loss (SNHL) is

thought to occur in approximately one third of patients who recover from Lassa. This is much higher than following infection with many other microorganisms known to cause hearing loss, for example herpes simplex virus, measles virus, syphilis and Toxoplasma. SNHL can occur in the acute phase of illness or following recovery, including following mild disease. The pathogenesis of the hearing loss is not fully understood; it is unclear if it is caused by direct viral damage or is immune-mediated (cellular or humoral), with conflicting evidence for and against both mechanisms. Due to the possibility that the mechanism is immune-mediated, it is uncertain whether SNHL may occur as a complication following immunization with a Lassa vaccine. For this reason, pure tone audiometry will be performed at baseline and participants who have abnormal hearing will be excluded from participation in the trial. This will also be performed at the end of the study and participants will be referred to a clinical audiology service for full evaluation should any abnormality be identified before or during the trial.

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

When is the study starting and how long is it expected to run for?
June 2024 to August 2026

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

Who is the main contact?
Dr. Reyna Sara Quintero Barceinas, sara.quinterobarceinas@paediatrics.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011278

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 66329

Study information

Scientific Title
A phase 1, first-in-human safety and immunogenicity study of a Lassa fever vaccine, ChAdOx1 LassaJ, in healthy volunteers aged 18 – 55 years in the UK

Study objectives
To assess the safety and tolerability of ChAdOx1 LassaJ in healthy volunteers aged 18 – 55 years

Exploratory objectives
1. Gene expression studies and further exploratory assays/analyses relevant to vaccine immunogenicity may be carried out.
2. Lassa-specific antibody response and functionality may be assessed at timepoints not included in secondary objectives.
3. Cellular immune response may be measured by intracellular cytokine staining (ICS), proliferation, and/or interferon ELISpots.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending submission

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention, Treatment, Safety

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

Health condition(s) or problem(s) studied
Lassa virus

Interventions
The study's main purpose is to assess the vaccine's safety and the immune response that develops in vaccinated people. The study will recruit up to 31 healthy people aged 18 to 55 years old. Participants will be screened for eligibility using an online questionnaire and a telephone call, followed by an in-person medical assessment. The first 6 eligible participants will have two doses of ChAdOx1 LassaJ suspension for intramuscular injection vaccine (total dose 10 x 10^10 viral particles (5 x 10^10 viral particles per dose) 12 weeks apart. The following 25 participants will be divided into two groups. One group (up to 20 participants) will then receive intramuscular injections of the Lassa vaccine given 12 weeks apart. The other group (5 participants) will receive two injections of saline (a placebo) given 12 weeks apart. Participants will be followed up for 1 year from the time of first vaccination. During this time they will have blood tests and medical checks performed to identify what response their immune system has made to the vaccine and to see if the vaccine could potentially provide some protection from Lassa fever in the future.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
1. The occurrence of solicited local and systemic reactogenicity signs and symptoms will be monitored and recorded for 7 days following each vaccination.
2. The occurrence of unsolicited adverse events (AEs) will be monitored and recorded for 28 days following each vaccination.
3. The occurrence of abnormal safety laboratory measures will be assessed through laboratory tests for the duration of the study period.
4. The occurrence of serious adverse events (SAEs) and adverse events of special interest (AESIs) will be monitored and recorded for the duration of the study period.

Secondary outcome measures
Serological response measured using antigen-specific T cell ELISpot assays, ELISA, or other relevant assays before and after vaccination

Overall study start date
04/06/2024

Completion date
30/08/2026

Eligibility

Key inclusion criteria
Participants must satisfy all the following criteria to be eligible for the study:
1. Adults aged between 18 to 55 years (inclusive) at the time of screening.
2. Medically healthy,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.
3. Able to attend the scheduled visits and to comply with all study procedures,including internet

access for the recording of electronic diary cards.
4. Willing and able to give informed consent for participation in the study.
5. Willing to allow confirmation of past medical history either through provision of or access to a medical record summary or other medical documentation or allowing investigators to obtain a copy of their medical history from their GP practice or accessed via electronic patient records.
6. Willing to allow their GP and/or consultant,if appropriate,to be notified of participation in the study.
7. Willing to provide their national insurance number or passport number to be registered on The Over-Volunteering Prevention System (TOPS).
8. Agreement to refrain from blood donation during the study.
9. For participants of childbearing potential only (as defined in section 12.10): willing to use effective contraception for the duration of the study AND to have a pregnancy test on the days of screening,vaccination and at the end of the study. The pregnancy tests taken prior to vaccination must be negative.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
Planned Sample Size: 31; UK Sample Size: 31

Key exclusion criteria
Participants may not enter the study if any of the following apply:
1. Receipt of an investigational product within 12 weeks prior to enrolment or planned within the trial period.
2. Participation in another research study,in which procedures performed could compromise the integrity of this study (such as significant volumes of blood taken) or are planning to do so within the trial period.
3. History of previous confirmed or suspected Lassa fever or another arenavirus infection.
4. Travel to a Lassa Endemic Country in West Africa within the 12 months prior to enrolment into the study or intended travel to an Endemic Country during the course of the study
5. Administration of immunoglobulins and/or any blood products within three months preceding the planned administration of the vaccine candidate.
6. Any confirmed or suspected immunosuppressive or immunodeficient state,including HIV infection; asplenia; severe infection(s); 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 consecutive days within three months preceding the planned administration of the vaccine candidate).
7. History of anaphylaxis in relation to vaccination.

8. 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.
9. History of hereditary angioedema,acquired angioedema,or idiopathic angioedema.
10. History of cancer (except basal cell carcinoma of the skin and cervical carcinoma in situ).
11. History of any serious psychiatric condition likely to affect participation in the study.
12. Participants who are pregnant,breastfeeding or lactating,or are planning pregnancy during the study.
13. History of a bleeding disorder (e.g.,Factor deficiency,coagulopathy,or platelet disorder),or prior history of significant bleeding or bruising following IM injections or venepuncture.
14. 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.
15. History of capillary leak syndrome.
16. History of Guillian-Barre syndrome,transverse myelitis or other neuroinflammatory syndrome.
17. Moderate,severe and/or uncontrolled cardiovascular disease,respiratory disease, gastrointestinal disease,liver disease,renal disease,haematological,immunological,endocrine disorder,or neurological illness (note,mild well-controlled co-morbidities in a healthy participant are acceptable as judged by the Investigator).
18. Suspected or known current alcohol abuse,as per investigators discretion.
19. Suspected or known injecting drug use within the 5 years preceding enrolment.
20. Acute or chronic hepatitis B or hepatitis C infection.
21. HIV infection.
22. Any clinically significant finding on screening that is either unlikely to resolve or does not resolve (for example on repeat testing at the discretion of an Investigator) within the recruitment timeline of the study.
23. Any other significant disease,disorder or finding which may significantly increase the risk to the volunteer if included in the study,affect the ability of the volunteer to participate in the study,or impair interpretation of the study data.
24. Study site staff or a partner or dependent child of study site staff.
25. Prior history of Sensorineural Hearing Loss
26. Hearing loss of 30 dB or greater in at least 3 sequential frequencies as determined by pure-tone audiometry

Date of first enrolment
20/07/2025

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Oxford Vaccine Group, University of Oxford
Centre for Clinical Vaccinology & Tropical Medicine (CCVTM), Churchill Hospital
Oxford
United Kingdom
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Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics & Assurance (RGEA) Team, 1st floor, Boundary Brook House, Churchill Drive, Headington
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United Kingdom
OX3 7GB
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Sponsor type
University/education

Website
https://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

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

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Conference presentation
3. Publication on website
4. Other publication
5. Submission to regulatory authorities

Participants will not be identifiable from shared or published data. De-identified participant data will be made available upon requests directed to the chief investigator. Proposals will be reviewed and approved by the sponsor, chief investigator, and collaborators on the basis of scientific merit. After approval of a proposal, data can be shared through a secure online platform after signing a data access agreement.

Intention to publish date
01/09/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date