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ViTaL02: A study of a new vaccine against Lassa

Submission date
03/09/2025

Recruitment status
Recruiting

Registration date
06/11/2025

Overall study status
Ongoing

Last Edited
05/10/2026

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 caused by a virus spread by rodents that poses a threat to approximately 59 million people living in West Africa. Whilst the majority of individuals who develop it only have mild symptoms, for some it can lead to long-term disability or even be fatal. There are currently no vaccines or licensed treatments for Lassa fever. Given the significance of the infection for some, the potential long-term consequences for the survivors and the number of people at risk of this disease, it is important to find a vaccine to help protect against the disease. This study is testing a new vaccine called ChAdOx1 LassaJ to see if it is safe and can stimulate the body to produce an immune response that may help fight the Lassa virus. The ChAdOx1 LassaJ vaccine is similar to the Oxford-AstraZeneca COVID-19 vaccine, over 3 billion doses of which have been used worldwide.

Who can participate?
Healthy volunteers aged 18 – 55

What does the study involve?
Involvement will last approximately one year and will include:
• Screening visits: The screening visit is the initial appointment during which the study team assesses whether potential participants are eligible to take part in the study. Before any procedures, the study will be explained in detail, and any questions the participant may have will be answered. If the individual agrees to participate, written informed consent will be obtained either directly from the participant or via an impartial witness if necessary.

Following consent, the participant's health will be reviewed through a series of assessments, including a physical examination, a hearing test, and blood sample collection. Approximately 15 ml (equivalent to about three teaspoons) of venous blood will be drawn. For women of childbearing potential, a urine pregnancy test will also be conducted during the screening visit. If the participant is deemed eligible based on these assessments, they will be invited to attend subsequent study visits.

• Vaccination visits: A physical check-up will be performed where ~ 50ml (10 teaspoons) of venous blood will be collected, and, for women with childbearing potential, a urine pregnancy test will be performed to confirm that they are not pregnant. Everyone in the study will receive two injections in their arms, 12 weeks apart. They will receive one or two injections of either:

o The ChAdOx1 LassaJ vaccine (study vaccine)
o A placebo injection, which is sterile salt water only

Participants will be asked to stay at the study clinic for at least 30 minutes after each injection so that they can be monitored.

• Community visits: For the first 6 days after each vaccination, participants will also be visited every day by the study team, who will ask questions about their health and measure their temperature and check for any reactions to the vaccine.

• Follow-up visits: Participants will attend several follow-up visits over the course of one year to monitor their health and collect blood samples. The volume of blood samples at the follow-up visits will range from ~ 10ml to 50ml (2 to 10 teaspoons), depending on the study visit. These visits are to assess the vaccine's safety and whether the participant's body produces an immune response to the vaccine. They will have to attend follow-up visits 7, 14 and 28 days after each injection – and two later visits - 6 months and 1 year after their first injection. They will also receive a repeat hearing test as part of the 1-year post-vaccination visit.

• Participants might come to the clinic for an extra visit if medically needed.

What are the possible benefits and risks of participating?
Potential benefits:
The recruitment population will not directly benefit from participation in the study. This is because an individual's risk of becoming infected with Lassa Fever is currently low. Furthermore, the clinical effects of ChAdOx1 LassaJ against Lassa fever infection have not been established, and will not be established by this study.

Participants enrolled on the study will receive free medical attention during the entire study period. This will include treatment of any symptoms caused by the vaccine, as well as treatment for any acute illnesses occurring during the study period, free of charge.

Potential risks:
This vaccine is only just beginning to be administered to humans.

Possible vaccine side effects or risks:
• Local Reactions: Mild discomfort at the injection site, such as pain, redness, swelling, itchiness, or warmth. These symptoms usually resolve within a few days.
• General Reactions: Flu-like symptoms such as fever, chills, fatigue, headaches, muscle aches, joint pains, nausea, and feeling unwell may occur in the first 24–48 hours after vaccination.
• Rare but Serious Reactions: Rare but potentially serious reactions that could result in death or serious illness have been linked to similar vaccines such as the Oxford AstraZeneca COVID-19 vaccine. These include:
o A rare blood clot disorder (vaccine-induced thrombocytopenia and thrombosis (VITT)) has been associated with similar vaccines.
o A rare side effect of low blood platelets, which can be associated with bleeding, has been reported with similar vaccines. Platelets are tiny pieces of cells in your body that stick together like a natural bandage to help stop bleeding.
o Capillary leak syndrome, a serious condition that causes swelling in the limbs and body. It happens when small blood vessels in the body allow more fluid than normal to pass through their walls.
o Severe allergic reactions, which are extremely rare but can be life-threatening.
o Serious neurological conditions, which affect the brain and nervous system, have been

reported after similar vaccines. These conditions can result in paralysis, weakness, confusion, seizures and/or other disabilities.
Other risks:
• Blood sampling may cause slight pain, bruising, or occasionally light-headedness or fainting.
• During the study or screening visit, something may be found out about the participant's health that they weren't aware of. The screening visit tests include testing for HIV, hepatitis B and hepatitis C viruses. If a new health issue is found, the study team will talk to the participant about it and, with their permission, arrange for this to be looked into and treated if needed.

Where is the study run from?
The Kintampo Health Research Centre, Kintampo, Ghana. The study is sponsored by the University of Oxford, UK.

When is the study starting and how long is it expected to run for?
October 2026 to January 2029

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

Who is the main contact?
Prof. Maheshi Ramasamy (Chief Investigator), info@ovg.ox.ac.uk
Dr Seyram Kaali (Principal Investigator), kaali.seyram@kintampo-hrc.org

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
PACTR202506787993203

Study information

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

Acronym
ViTaL02

Study objectives
This phase 1 study aims to assess the safety, tolerability and immunogenicity of ChAdOx1 LassaJ in healthy volunteers aged 18 – 55.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 16/01/2026, Oxford Tropical Research Ethics Committee (OxTREC) (Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; (+44) 01865 (2)82585; oxtrec@admin.ox.ac.uk), ref: 1726163

2. Approved 16/12/2025, Kintampo Health Research Centre Institutional Ethics Committee (P.O. Box 200, Kintampo, PO Box 200, Kintampo, Bono East, Ghana; +2330556847860; ethics@kintampo-hrc.org), ref: KHRCIEC/2025-05

3. Approved 26/01/2026, Ghana Health Service Ethics Review Committee (Research and Development Division, Ghana Health Service, P.O Box MB 190, Accra, P.O Box MB 190 Accra, Ghana; +233503539896; ethics.research@ghs.gov.gh), ref: GHS-ERC: 023/08/25

Primary study design
Interventional

Study design
Phase I safety tolerability and immunogenicity trial

Study type(s)
Safety, Other

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

Interventions
This is a phase I trial to assess the safety, tolerability, and immunogenicity of both a one-dose and two-dose regimen of ChAdOx1 LassaJ in healthy volunteers aged 18-55 years. There will be an initial lead-in cohort (cohort 1) of 6 participants who will each receive 2 intramuscular doses of LassaJ given 12 weeks apart. This will be followed by a participant-observer blinded cohort of 45 participants (cohort 2). Participants recruited to cohort 2 will be randomly allocated to one of three groups in a 4:4:1 ratio. Randomisation will be through REDCap, with a manual back-up system in place if REDCap is unavailable. The first 6 participants recruited to the trial will be enrolled into cohort 1, an open-label lead-in group. All subsequent participants (cohort 2, n=45) will be recruited into three groups randomly using a 4:4:1 randomisation ratio.

The first group (up to 20 participants) will receive intramuscular injections of the Lassa vaccine given 12 weeks apart. The second group (up to 20 participants) will receive a single dose of the Lassa Vaccine followed by a single dose of Saline Placebo 12 weeks later. The final group (5 participants) will receive two doses of a Saline Placebo injection given 12 weeks apart.

There are 2 doses of ChAdOx1 LassaJ (5 x 10^10 viral particles (vp) per dose administration), 1 dose of ChAdOx1 LassaJ (5 x 10^10 virus particles) and 1 dose of placebo (normal saline), or two doses of placebo (normal saline), given at 0 and 84 days (3-month interval). Given as intramuscular injections.

Intervention Type
Biological/Vaccine

Phase
Phase I

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

Primary outcome(s)
The primary outcome measures are assessed using data collected in electronic Case Report Forms (eCRF) at one timepoint:
1. Occurrence of solicited local and systemic reactogenicity signs and symptoms for 28 days following each vaccination
2. Occurrence of unsolicited adverse events (AEs) for 28 days following each vaccination
3. Occurrence of abnormal safety laboratory measures for the duration of the study period
4. Occurrence of serious adverse events (SAEs) and adverse events of special interest (AESIs) for the duration of the study period

Key secondary outcome(s)
Assessment of serological response measured using antigen-specific T cell ELISpot assays, ELISA or other relevant assays, before and after vaccination

Completion date
31/01/2029

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 the investigator's 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 comply with all study procedures
4. Willing and able to give informed consent for participation in the study
5. Able to provide a reliable past medical history confirmed, where necessary, at the investigator' s discretion, by the participant's usual health care provider
6. Willing to allow the usual health care provider, if appropriate, to be notified of participation in the study.
7. Agreement to refrain from blood donation during the study
8. For participants of childbearing potential only (as defined by protocol section 12.10): willing to use effective contraception for the duration of the study AND to have a pregnancy test on the day of screening and vaccination days. The pregnancy tests taken before vaccination must be negative.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Participants may not enter the study if any of the following apply:
1. Receipt of an investigational product within 12 weeks before 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 or previous participation in another Lassa vaccine trial.
4. Administration of immunoglobulins and/or any blood products within three months preceding the planned administration of the vaccine candidate.
5. 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).
6. History of anaphylaxis in relation to vaccination.
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.
8. History of hereditary angioedema, acquired angioedema, or idiopathic angioedema.
9. History of cancer (except basal cell carcinoma of the skin and cervical carcinoma in situ).
10. History of any serious psychiatric condition likely to affect participation in the study.
11. Participants who are pregnant, breastfeeding or lactating, or are planning pregnancy during the study.
12. 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.
13. 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.
14. History of capillary leak syndrome.
15. History of Guillian-Barre syndrome, transverse myelitis or other neuroinflammatory syndrome.
16. 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).
17. Suspected or known current alcohol abuse, as per investigator's discretion.
18. Suspected or known recreational drug use within the 5 years preceding enrolment.
19. Positive laboratory evidence of acute or chronic hepatitis B or hepatitis C infection.
20. Positive laboratory evidence of HIV infection.
21. 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.
22. 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.
23. Study site staff or a partner, or dependent child of study site staff.
24. Prior history of Sensorineural Hearing Loss
25. Hearing loss of 30dB or greater in at least 3 sequential frequencies as determined by pure-tone audiometry
26. Use of traditional herbal medicine within 3 months of enrolment in the study, which, in the opinion of the investigator, could impact the integrity of the trial.

Date of first enrolment
14/10/2026

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
Ghana

Study participating centre
Kintampo Health Research Centre
No. 2 Health Loop
Kintampo, Bono East
Ghana
PO Box 200

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
The datasets generated during and/or analysed during the current study will be available upon request from the Chief Investigator, Prof Maheshi Ramasamy, info@ovg.ox.ac.uk.

• The type of data that will be shared: Anonymised data
• Timing for availability: Once the trial data has been published
• Whether consent from participants was required and obtained: Consent for sharing anonymised data for future research will be obtained as part of the main trial consent
• Comments on data anonymization: All participants will be allocated a unique trial identifier. Personally identifiable information will be held securely by the trial site solely for trial delivery and participant management, and will not be shared outside the site. Access to this information will be restricted to those authorised to do so for audits and monitoring, e.g. monitors, regulators and Sponsor. Only pseudonymised data (with direct identifiers removed) will be shared with the sponsor. If data are shared with external researchers for future ethically approved studies, they will be further anonymised by removing direct identifiers and minimising indirect identifiers
• Any ethical or legal restrictions: Ethical approval for future research may be required by the Institutional and Ghanaian ethics committees
• Any additional comments: None

IPD sharing plan summary

Available on request