

Developing a vaccine against Bundibugyo ebolavirus

Submission date 22/06/2026	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 13/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 18/09/2026	Condition category Infections and Infestations	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

On 17th May 2026, the World Health Organisation declared a public health emergency of international concern after cases of severe fever and death were detected in the Democratic Republic of the Congo (DRC). The emergency is being caused by Bundibugyo virus (BVD), which is a species of Ebola virus, and like all species of Ebola, it causes a severe and often fatal infection in humans. Normally carried by fruit bats, it can cross over into humans through contact with infected animals. Once this occurs, it can then spread from person to person through direct contact with infected body fluids. Unlike another species of Ebola (Zaire ebolavirus), there are no licensed vaccines or medications to protect against BDBV infection. It is therefore vital that we develop a safe and effective vaccine against Bundibugyo virus disease (BVD) as soon as possible.

Who can participate?

Volunteers aged between 18 and 55 years old and in good health

What does the study involve?

The first 10 participants to be enrolled will all get a single dose of the vaccine. The next 40 participants will either receive a single dose of the vaccine or a saltwater placebo – neither they nor the study team will know which they have received until the end of the study. In addition, the first 10 participants to be enrolled will get a booster dose of the vaccine 6 months after the first dose. All participants will be followed up for a year and will attend a number of visits where safety can be checked and blood tests taken.

The main purpose of this study is to assess the safety and tolerability of the study vaccine (ChAdOx1 Ebola BDBV Vaccine [Recombinant]), meaning researchers will carefully monitor any side effects, symptoms or changes in health that occur after vaccination and determine how well participants tolerate the vaccine.

What are the possible benefits and risks of participating?

The recruitment population will not directly benefit from participation in the study, as the clinical efficacy of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) has not been established and will not be established by this study. Participants will be informed that they should not anticipate any protection from potential future BDBV infection following participation in this

study. No specific additional medical care will be provided through participation, and medical procedures are performed with the aim of determining eligibility and safety during the trial.

Specific risks related to the ChAdOx1 Ebola BDBV Vaccine (Recombinant):

The most likely side effects that recipients of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) may experience are short-lived local reactions (primarily injection site tenderness or pain) and systemic reactions (fatigue, headache, malaise, and 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 vaccine-induced thrombocytopenia and thrombosis (VITT), 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 the ChAdOx1 Ebola BDBV Vaccine (Recombinant) 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.

Given existing safety data which supports the use of ChAdOx1 nCoV-19 in pregnant women, there is no reason to believe the ChAdOx1 Ebola BDBV Vaccine (Recombinant) would be harmful to women or the foetus during pregnancy. However, as yet there are no data on the use of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) in pregnancy. Therefore, pregnant women will be excluded from the trial, and women of childbearing potential will be required to use highly effective contraception to take part.

Other trial-related risks:

Blood sampling during the trial may cause slight pain, bruising, light-headedness or fainting. The volume of blood given in the trial is less than that taken by regular blood donors over the same period, so it should not compromise healthy participants. Intramuscular injections carry a risk of bleeding in patients with very low platelet counts or coagulopathies. A baseline full blood count (with a platelet count) taken prior to vaccination would allow exclusion of volunteers with this risk.

Where is the study run from?

Oxford Vaccine Group, Churchill Hospital (UK)

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

July 2026 to December 2027

Who is funding the study?

The Coalition for Epidemic Preparedness Innovations (CEPI)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific

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Additional identifiers**Integrated Research Application System (IRAS)**

1014429

Central Portfolio Management System (CPMS)

74638

Study information**Scientific Title**

A Phase Ia randomised double-blinded placebo-controlled study of a Bundibugyo virus disease vaccine, ChAdOx1 Ebola BDBV Vaccine (Recombinant), in healthy volunteers aged 18–55 years in the UK

Acronym

BD-Ebov-01

Study objectives**Primary Objective:**

To assess the safety and tolerability profile of a single dose of ChAdOx1 Ebola BDBV Vaccine (Recombinant) in healthy volunteers

Secondary Objective:

To assess the immunogenicity of a single dose of ChAdOx1 Ebola BDBV Vaccine (Recombinant) in healthy volunteers

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 13/07/2026, London-Brent Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8000; brent.rec@hra.nhs.uk), ref: 26/LO/0481

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Single

Purpose

Prevention

Study type(s)**Health condition(s) or problem(s) studied**

Bundibugyo ebolavirus

Interventions

This is a first-in-human Phase Ia trial to assess the safety, tolerability, and immunogenicity of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) in healthy volunteers aged 18-55 years. The trial will consist of two phases.

In phase A, an initial open-label cohort (cohort 1) of 10 participants will all receive a single dose of the ChAdOx1 Ebola BDBV Vaccine (Recombinant). Cohort 1 will be followed by a participant-observer blinded cohort of 40 participants (cohort 2), randomised 3:1 to receive either a single dose of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) or a saline placebo.

In phase B, the 10 healthy volunteers from Cohort 1 of the main study will receive a booster dose of the ChAdOx1 Ebola BDBV Vaccine (Recombinant) at 6 months following prime vaccination to achieve exploratory trial objectives.

Participants in cohort 1 will have a screening visit, two vaccination visits and nine in-person follow-up visits. Cohort 2 will have a screening visit, one vaccination visit and six in-person follow-up visits.

Intervention Type

Biological/Vaccine

Phase

Phase I

Drug/device/biological/vaccine name(s)

ChAdOx1 Ebola BDBV Vaccine (Recombinant)

Primary outcome(s)

1. Occurrence of solicited local and systemic reactogenicity signs and symptoms measured using the electronic diary provided to participants at for 7 days following vaccination
2. Occurrence of unsolicited adverse events (AEs) measured using self-report by participants in the eDiary up to 7 days following each vaccination, or collected at visits up to 28 days following each vaccination
3. Occurrence of abnormal safety laboratory measures measured using the electronic clinical database at for the duration of the study period
4. Occurrence of serious adverse events (SAEs) and adverse events of special interest (AESIs) measured using collection at visits until the end of the study

Key secondary outcome(s)

Completion date

31/12/2027

Eligibility

Key inclusion criteria

1. Adults aged between 18 and 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 access it 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: willing to use highly effective contraception for the duration of the study AND to have a pregnancy test on the days of screening and vaccination and at the final visit. The pregnancy tests taken prior to vaccination must be negative.

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

Total final enrolment

40

Key exclusion criteria

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 exposure to a different study IMP or significant volumes of blood taken, or are planning to do so within the trial period.
3. History of previous confirmed or suspected filovirus infection.
4. History of travel within 42 days of enrolment, or planned travel within study period, to countries currently reporting filovirus outbreaks as declared by the WHO (e.g., the Democratic Republic of the Congo and Uganda)
5. Prior receipt of a vaccine targeting filoviruses, including licensed and investigational vaccines
6. Prior receipt of a ChAdOx1- or ChAdOx2-vectored vaccine within 2 years of enrolment (updated 25/08/2026 to add the time restriction)
7. Administration of immunoglobulins and/or any blood products within 3 months preceding the planned administration of the vaccine candidate.
8. 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).
9. History of anaphylaxis or severe reaction in relation to vaccination.
10. 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.
11. History of hereditary angioedema, acquired angioedema, or idiopathic angioedema.
12. History of cancer (except basal cell carcinoma of the skin and cervical carcinoma in situ).
13. History of any serious psychiatric condition likely to affect participation in the study.
14. Participants who are pregnant, breastfeeding or lactating or are planning pregnancy during the study.
15. 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.
16. 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.
17. History of capillary leak syndrome.
18. History of Guillain-Barre syndrome, transverse myelitis or other neuroinflammatory

syndrome.

19. History of currently active autoimmune conditions of any severity requiring treatment or on-going medical follow

20. Moderate, severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, haematological, immunological, endocrine disorder, or neurological illness. Well-controlled comorbidities in a healthy participant are acceptable as judged by the Investigator.

21. Suspected or known current alcohol abuse, as per investigator's discretion.

22. Suspected or known injecting drug use within the 5 years preceding enrolment.

23. Acute or chronic hepatitis B or hepatitis C infection.

24. 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.

25. 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.

26. Study staff or a partner or dependent child of study staff.

Date of first enrolment

20/07/2026

Date of final enrolment

14/09/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oxford Vaccine Group

Churchill Hospital, Annexe Reception, Centre for Clinical Vaccinology and Tropical Medicine
Oxford

England

OX3 7LE

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton NIHR Clinical Research Facility

Southampton

England

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Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

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

IPD sharing plan summary

Not expected to be made available