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A study of a new vaccine against Nipah virus in adults aged 18 to 55 years

Submission date
12/07/2023

Recruitment status
No longer recruiting

Registration date
20/10/2023

Overall study status
Completed

Last Edited
07/04/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
This is a trial of a new vaccine against the Nipah virus. Nipah virus is a potentially fatal infection that can cause severe breathing problems and abnormalities with the nervous system including the brain. It was first identified in 1999 in a large outbreak in Malaysia and Singapore which was caused by transmission from infected pigs to humans. Since then, outbreaks have occurred almost annually in Bangladesh with human-to-human spread. The virus has the potential to cause large outbreaks. There are no approved treatments or vaccines.
This study is of a vaccine called ChAdOx1 NipahB which has been developed by the University of Oxford. The vaccine is similar to the Oxford/AstraZeneca COVID-19 vaccine, however, the trial vaccine targets a component of the Nipah virus rather than the virus that causes COVID-19. This trial will be the first time the vaccine is given to humans. The purpose is to assess the safety and immune response.

Who can participate?
Healthy volunteers aged 18 to 55 years

What does the study involve?
Participants will be screened for eligibility with an optional online questionnaire and telephone call, followed by an in-person medical assessment. The first 6 eligible participants (cohort 1) will have two doses of vaccine 12 weeks apart. The following 45 participants (cohort 2) will be assigned, at random, to one of three groups. Group 1 will receive one dose of vaccine and one dose of sterile salt water, group 2 will receive two doses of vaccine, and group 3 will receive two doses of sterile salt water. The intramuscular injections will be given 12 weeks apart. The sterile salt water has no active ingredients which means it acts as a ‘placebo’. Apart from the researchers responsible for the randomisation, preparation and administration of the vaccine, the study team nor the participants will know whether vaccine or placebo were given until the end of the study. Participants will be followed up for 1 year from the first vaccination.
Following recruitment of the 51 participants in the main part of the study, the clinical trial was amended to add in a further 10 participants – the “Immunology Extension study”. This will allow further analysis of the early immune response resulting from the vaccine to be analysed, particularly within the first week of vaccination.

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 Nipah virus, but they will not directly receive any personal health benefit from the study or its procedures.
There is no risk of contracting the Nipah virus from the ChAdOx1 NipahB vaccine, and the participants will not be exposed to the Nipah virus at any point during this study. The researchers 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 has only been studied in animals 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, participants may experience 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, 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), transient myelitis, anaphylaxis/serious allergic reactions, capillary leak syndrome, and risk of bleeding with intramuscular administration. It is currently unknown whether these rare reactions may occur with other ChAdOx1 vaccines but investigators using ChAdOx1 NipahB 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 NipahB they should make the intended immune response against the Nipah protein. However, they may also make an immune response against ChAdOx1 itself. This theoretical risk could mean that the ChAdOx1 NipahB 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 NipahB 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, injection site inspected.
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.
As the researchers carry out medical tests throughout the trial it is possible that they will 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 NipahB 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?
July 2023 to January 2028

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

Who is the main contact?
Dr Lilli Hahn, info@ovg.ox.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2023-503872-25

Integrated Research Application System (IRAS)
1007433

Central Portfolio Management System (CPMS)
55896

Protocol serial number
OVG 2023/02

Study information

Scientific Title
A Phase I safety and immunogenicity study of a Nipah virus vaccine, ChAdOx1 NipahB, in healthy volunteers aged 18 to 55 years in the UK

Acronym
NIV001

Study objectives
Primary objective:
To assess the safety and tolerability of ChAdOx1 NipahB in healthy adult volunteers

Secondary objective:
To assess the immunogenicity of ChAdOx1 NipahB in healthy adult volunteers

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 19/10/2023, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; None provided; oxforda.rec@hra.nhs.uk), ref: 23/SC/0268

Study design
Double-blind randomized placebo-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Prevention, Safety

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

Interventions
The first six participants recruited to the trial will be enrolled to cohort 1. These 6 individuals will be non-randomly allocated to group A, an open-label lead-in group. These six participants will each receive a dose of 5 x 10e10 viral particles of ChAdOx1 NipahB intramuscularly on days 0 and 84 (12 weeks following the first vaccination). Participants will have in-person follow-up visits on days 2, 7, 14, 28 and 56 after each vaccination, as well as a final follow-up visit at 1 year following the first vaccination.

All subsequent participants (n = 45) will be recruited into cohort 2 and randomly allocated to either group 1, 2 or 3 using a 4:4:1 randomisation ratio, respectively. Randomisation will be performed using an electronic database. Cohort 2 will be placebo-controlled and conducted in an observer and participant-blind fashion. Group 1 will receive a dose of 5 x 10e10 viral particles of ChAdOx1 NipahB intramuscularly on day 0 followed by saline placebo on day 84; group 2 will receive a dose of 5 x 10e10 viral particles of ChAdOx1 NipahB intramuscularly on days 0 and 84, and group 3 will receive a dose of saline placebo intramuscularly on days 0 and 84. Participants will have in-person follow-up visits on days 14 and 28 and after each vaccination, as well as a final follow-up visit at 1 year following the first vaccination.

Added 07/04/2026:
An additional n = 10 participants will be recruited and non-randomly allocated into an open-label single-arm additional cohort (cohort 3).

Intervention Type
Biological/Vaccine

Phase
Phase I

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

Primary outcome(s)
1. Occurrence of solicited local reactogenicity signs and symptoms at 7 days following each vaccination (D0 to D6; V2 to V2+6)

2. Occurrence of solicited systemic reactogenicity signs and symptoms at 7 days following each vaccination (D0 to D6; V2 to V2+6)
3. Occurrence of unsolicited adverse events (AEs) at 28 days following each vaccination (D0 to D27; V2 to V2+27)
4. Occurence of abnormal safety laboratory measures; Cohort 1: D0, D2, D7, D14, D28, D56, V2, V2+2, V2+7, V2+14, V2+28, V2+56); Cohort 2: D0, D14, D28, V2, V2+14, V2+28
5. Occurrence of serious adverse events (SAEs) and adverse events of special interest (AESIs) for the whole duration of the study (D0 to V2+281)

Key secondary outcome(s))
NipahB glycoprotein G-specific serological response as measured by ELISA; Cohort 1: D0, D14, D28, D56, V2, V2+14, V2+28, V2+56, V2+281; Cohort 2: D0, D14, D28, V2, V2+14, V2+28, V2+281

Completion date
09/03/2026

Eligibility

Key inclusion criteria
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 course of the study
9. For women of childbearing potential only: willing to use effective contraception from one month prior to receiving the first dose of vaccine and for the duration of the study AND have a negative pregnancy test on the days of screening and vaccination

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Total final enrolment
61

Key exclusion criteria
1. Participation in another research study involving an investigational product or other study which includes procedures that could compromise the integrity of this study (such as significant volumes of blood already taken) within the 12 weeks prior to enrolment, or are planning to do so within the trial period
2. Previous receipt of another adenoviral-vectored vaccine (which includes the Oxford /AstraZeneca and Janssen COVID-19 vaccines) within the preceding year
3. Previous immunisation with an investigational Nipah vaccine
4. History of previous confirmed or suspected Nipah infection
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 3 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 (EDTA or magnesium chloride)
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. For women only: participants who are pregnant, breastfeeding or lactating, or are planning pregnancy during the course of 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. 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 defined by an alcohol intake of greater than 42 units per week
18. Suspected or known injecting drug use within the 5 years preceding enrolment
19. Detectable circulating hepatitis B surface antigen (HBsAg)
20. Seropositive for hepatitis C virus (antibodies to HCV)

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

Date of first enrolment
27/11/2023

Date of final enrolment
08/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Clinical Vaccinology & Tropical Medicine
University of Oxford
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OX3 7LE

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

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 2.0	10/10/2023	05/03/2024	No	No
Protocol file	version 3.0	02/05/2024	03/07/2024	No	No
Protocol file	version 4.0	16/08/2024	31/10/2024	No	No
Protocol file	version 5.0	17/01/2025	11/03/2025	No	No
Protocol file	version 5.1	18/03/2025	23/04/2025	No	No
Protocol file	version 5.2	25/03/2025	23/04/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes