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A study of a vaccine against Nipah Virus in adults aged 18 to 55 years in Bangladesh

Submission date
12/08/2025

Recruitment status
No longer recruiting

Registration date
17/10/2025

Overall study status
Ongoing

Last Edited
16/02/2026

Condition category
Infections and Infestations

[_] 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 study 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 vaccine targets a component of the Nipah virus rather than the virus that causes COVID-19. This study 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 by an in-person medical assessment. The first six eligible participants (cohort 1A) will have two doses of vaccine 12 weeks apart. The following 300 participants (cohort 2) will be assigned, at random, to one of three groups. Group 2A will receive two doses of vaccine, group 2B will receive one dose of vaccine and one dose of sterile salt water and group 2C will receive one dose of inactivated polio vaccine and one dose 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’. The approved inactivated polio vaccine could provide increased protection against polio, and is used as a control vaccine. Apart from the researchers responsible for the randomisation, preparation and administration of the vaccine, neither 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.

What are the possible benefits and risks of participating?
This study involves some potential risks. The vaccine in this study has so far only been tested in about 50 people in a study that started in the UK in 2024. This vaccine is still being tested to see

if it works and is safe and is not used in routine vaccination program.
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, 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. These include:
1. A rare blood clotting disorder (thrombosis with thrombocytopenia syndrome) has been associated with similar vaccines.
2. Capillary leak syndrome, a serious condition causing a lot of swelling in the limbs and body.
3. Severe allergic reactions, which are extremely rare but can be life-threatening.
4. Serious neurological conditions that can result in paralysis, weakness or other disability
Other risks:
Blood sampling may cause slight pain, bruising, or occasionally light-headedness or fainting.
During the study or screening visit, we might find something about your health that you weren't aware of. The screening visit tests include testing for HIV, hepatitis B and hepatitis C viruses. If we find a new health issue, we will talk to you about it and, with your permission, arrange for this to be looked into and treated if needed.
There is no risk of catching the Nipah virus from the vaccine in this study.

We do not yet know whether the new vaccine will work. So you should not assume that you have any protection against the Nipah virus from being in this study. If you are in the group that is given the approved polio vaccine then that could provide some increased protection against polio, although this vaccine is usually not needed for adults who have already been vaccinated against polio.
If you join the study, you will receive a free health assessment, diagnosis, and any necessary treatment at the icddr,b hospital. Once the study is completed, we will refer you to a suitable health care provider for any follow-up treatment you may need. Please note that the study team will not be able to cover the costs of long-term treatment for any conditions unrelated to the study that may be identified during this time.
The study includes insurance that will help cover medical expenses related to your participation, up to a specific limit. If the costs exceed this limit or if they are for conditions unrelated to the study, you would need to cover those additional costs yourself.
If you are not able to join the study but a health condition is identified during the screening, we will ensure you receive immediate care if needed. After that, we will refer you to a nearby health care provider for follow-up care. However, the study team cannot cover the costs of ongoing treatment in such cases.
By taking part in this study, you'll be helping to develop a vaccine for the Nipah virus, which could protect people in Bangladesh and other countries in the future.

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

When is the study starting and how long is it expected to run for?
May 2025 to December 2027

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

Who is the main contact?
Dr Lilli Hahn, lilli.hahn@paediatrics.ox.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
OVG2024/04

Study information

Scientific Title

A Phase IIa immunogenicity and safety study of a Nipah virus vaccine, ChAdOx1 NipahB, in healthy volunteers aged 18 to 55 years in Bangladesh

Acronym
NIV002

Study objectives
Primary immunogenicity:
To assess the immunogenicity of ChAdOx1 NipahB in a one and two-dose schedule in adults, by measurement of ELISA responses to Nipah glycoprotein G at 28 days post each dose

Primary safety:
To assess the safety and tolerability of ChAdOx1 NipahB in healthy volunteers aged 18-55 years

Secondary:
To assess the kinetics and durability of antibody responses to Nipah glycoprotein G in a one- and two-dose schedule of ChAdOx1 NipahB

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 22/05/2025, Oxford Tropical Research Ethics Committee (OxTREC) (Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 282585; oxtrec@admin.ox.ac.uk), ref: 1240774

2. Approved 08/05/2025, icddr,b Institutional Review Board (MA Salam Khan, IRB Coordinators, icddrb, Mohakhali, Dhaka, 1000, Bangladesh; +880 (0)22222 77084; salamk@icddrb.org), ref: PR-25005

Primary study design
Interventional

Study design
Single-site double-blind randomized controlled trial with an open-label non-randomised lead-in cohort

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 six individuals will be non-randomly allocated to group 1A, 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). Community visits will occur in the evening of the day of vaccination and subsequently daily in the week following each vaccination. Participants will have in-person follow-up visits on days 7, 14, and 28 after each vaccination, as well as a final follow-up visit at 1 year following the first vaccination.

All subsequent participants (n = 300) will be recruited into cohort 2 and randomly allocated to either group 2A, 2B or 2C using a 5:5:2 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 2A will receive a dose of 5 x 10e10 viral particles of ChAdOx1 NipahB intramuscularly on days 0 and 84; group 2B will receive a dose of 5 x 10e10 viral particles of ChAdOx1 NipahB intramuscularly on day 0 followed by saline placebo on day 84, and group 2C will receive a dose of inactivated polio vaccine intramuscularly on day 0 followed by saline placebo on day 84. Community visits will occur in the evening of the day of vaccination and subsequently daily in the week following each vaccination. Participants will have in-person follow-up visits on days 7, 14, and 28 after each vaccination, as well as a final follow-up visit at 1 year following the first vaccination.

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
ChAdOx1 NipahB, inactivated polio vaccine

Primary outcome(s)
Primary Safety Outcome Measures:
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 D28; V2 to V2+28)
4. Occurence of abnormal safety laboratory measures (D0, D7, D14, D28, V2, V2+7, 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)

Primary Immunogenicity Outcome Measure:
1. NipahB glycoprotein G-specific serological response as measured by ELISA (D0, D28, V2, V2+28)

Key secondary outcome(s)
NipahB glycoprotein G-specific serological response as measured by ELISA (D0, D7, D14, D28, V2, V2+7, V2+14, V2+28, V2+281)

Completion date
31/12/2027

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 comply with all study procedures.
4. Willing and able to give informed consent for participation in the study.
5. Agreement to refrain from blood donation during the course of the study.
6. For women of childbearing potential only (as defined by protocol section 8.5): 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
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
306

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 immunisation with an investigational Nipah vaccine.
3. Reported or documented history of previous confirmed or suspected Nipah infection.
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 (EDTA or magnesium chloride).
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. For women only: participants who are pregnant, breastfeeding or lactating, or are planning pregnancy during the course of 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. 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)
16. Suspected or known current alcohol abuse as defined by an alcohol intake of greater than 42 units per week.
17. Suspected or known injecting drug use within the 5 years preceding enrolment.
18. Detectable circulating hepatitis B surface antigen (HBsAg).
19. Seropositive for hepatitis C virus (antibodies to HCV).
20. 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.
21. 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.

Temporary Exclusion Criteria:
The following applies to both vaccination visits. If the temporary exclusion resolves within the time constraints of the trial visits, the participant can be enrolled and/or progression in the trial can continue.
1. Receipt of any systemic corticosteroid (or equivalent) treatment within 14 days prior to vaccination, or for more than 7 days consecutively within the previous 3 months.
2. Febrile illness (oral temperature ≥37.5°C) or systemically unwell on the day of vaccination.
3. Receipt of systemic antibiotics will result in vaccination being postponed until 7 days after the last antibiotic dose. This does not apply to topical antibiotic preparations.
4. Use of antipyretics in the 4 hours prior to vaccination.
5. Occurrence of a laboratory adverse event, which in the opinion of the Investigator, requires further time and/or investigation to resolve or stabilise prior to a dose of vaccine being administered.
6. Occurrence of any illness or adverse event, which in the opinion of the Investigator, requires of further time and/or investigation to resolve or stabilise prior to a dose of vaccine being administered.
7. Receipt of other vaccines. These must be administered 30 days before or after study vaccines EXCEPT influenza and COVID-19 vaccines, which may be given 14 days before or after study vaccines.

Date of first enrolment
12/10/2025

Date of final enrolment
03/02/2026

Locations

Countries of recruitment
Bangladesh

Study participating centre
icddr,b
GPO Box 128
Dhaka
Bangladesh
1000

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

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

Participant data will be made available when the trial is complete, upon requests directed to the trial's Chief Investigator Brian Angus (brian.angus@ndm.ox.ac.uk) or upon written approval of the sponsor. After approval of a proposal, data can be shared through a secure online platform. All data shared will be anonymised. The type of data available upon request includes datasets generated during and/or analysed during the current study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1		16/02/2026	No	No