Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Tel: 01865 611400 info@ovg.ox.ac.uk www.ovg.ox.ac.uk

PARTICIPANT INFORMATION SHEET (COHORT 4 ONLY)

NIV001: A study of a new vaccine against Nipah Virus in adults aged 18 to 55

We will recruit a further 20 people aged 18-55 years to take part in a phase I study of a new vaccine against **Nipah virus**. Our vaccine is called **ChAdOx1 NipahB**. 61 people have already been recruited to the earlier part of the study (cohorts 1, 2, and 3), which was the first time this vaccine had been used in people. We are now recruiting up to an **extra 20 people** to have two doses of the ChAdOx1 NipahB vaccine and to **donate plasma on two or three occasions.**

There is no risk of contracting Nipah virus from the vaccine itself, and you will not be exposed to Nipah virus at any point during this study.

Study Name	NIV001
Who can take part?	- Adults aged between 18 and 55 years in good health. - You must be **eligible to donate blood or plasma to take part in this trial** - You must **not have previously had the Oxford AstraZeneca COVID-19 vaccine** - Full inclusion criteria are explained on page 6.
Vaccine being tested	Two doses of ChAdOx1 NipahB given as an injection into the arm muscle.
Total participants	81 (cohort 1 = 6, cohort 2 = 45, cohort 3 = 10, **cohort 4 = up to 20**)
Study Aims	To test safety and immune response to the vaccine
Chief Investigator / Principal Investigator	Professor Brian Angus
Trial Location	**Trial Location**: Oxford Vaccine Group, University of Oxford Centre for Clinical Vaccinology and Tropical Medicine Churchill Hospital, Headington, Oxford, OX3 7LE **Plasma Donation Visits**: NHS Blood and Transplant – Reading Blood Donor Centre, Reading Bridge House, George St, Reading, RG1 8LS
Reimbursement	Participants will be reimbursed £110 for their screening visit and each vaccination visit. A reimbursement of £90 will be provided per follow up visit and £180 per plasma donation visit. Upon completion of each diary card participants will be reimbursed a further £30. Participants in Cohort 4 who complete all study visits will receive the following total payments: • Participants assigned 2 plasma donation visits will receive £1,020 • Participants assigned 3 plasma donation visits will receive £1,200 An additional £90 reimbursement will be provided for any unscheduled visits.
Risks of participation	Short-lived post-vaccine symptoms may occur, such as mild arm discomfort and fever. A full discussion of risks, including rare but serious reactions, is included here (page 14). The risks associated with plasma donation are also described on page 17. As this is a phase 1 study we will monitor the safety of participants closely.
Benefits of participation	By participating in this trial, you will help research into the development of a safe and effective vaccine to protect against Nipah virus, but you will not directly receive any personal health benefit from the study or its procedures.

Cohort 4 (the group currently being recruited) will have 1 screening visit, 2 vaccination visits, 2 or 3 plasma donation visits and 3 follow up visits over a period of up to 7 months.

COHORT 4	Screening visit	Plasma donation* (pre-vac)	Vaccine 1	Day 28 Follow up	Plasma donation 1	Vaccine 2 (Day 84)	Vac2 + 14 days Follow up	Plasma donation 2	D182 Follow up

Detailed Trial Visit Timeline

<u>Cohort 4</u> (the NEW group currently being recruited)

Visit	What to expect at the visit
Online Pre-Screening Questionnaire	If you decide that you would like to take part, we will ask you to complete a short set of online questions that cover some of the key criteria for participation in the trial. We will ask for your consent to access your medical and vaccination records from your GP or NHS database to assess whether you are eligible for the trial.
Pre-screening Phone-call	If you appear suitable from the pre-screening questionnaire, a member of the study team may contact you by telephone to discuss the study and answer any questions you may have. We will then book you in for an in-person screening visit.
Screening Visit	Consent discussion and sign consent form, ID check and TOPS registration, next of kin details, review medical history and inclusion/exclusion criteria, physical examination, vital signs, height and weight, blood test and urine pregnancy test (if appropriate).
Plasma donation *(pre-vac)	**Only some participants (approximately 3 to 5 individuals) will be asked to attend for the pre-vaccination plasma donation session** Attend blood donation centre for plasma donation eligibility check and plasma donation.
Day 0 Vaccination Visit 1	Review inclusion/exclusion criteria, vital signs, blood test, urine pregnancy test (if appropriate), receive vaccine, remain in clinic for at least 30 minutes post-vaccine, eDiary explained and started.
Day 28 Follow up	Follow up medical questions, eDiary reviewed, vital signs, blood test.
Plasma donation 1	Attend blood donation centre for plasma donation eligibility check and plasma donation.
Day 84 Vaccination visit 2	Review inclusion/exclusion criteria, vital signs, blood test, urine pregnancy test (if appropriate), receive vaccine, remain in clinic for at least 30 minutes post-vaccine, eDiary explained and started.
V2 + 14 days Follow up	Follow up medical questions, eDiary reviewed, vital signs, blood test.
Plasma donation 2	Attend blood donation centre for plasma donation eligibility check and plasma donation.
Day 182 Follow up	Final study visit: Follow up medical questions, blood test, urine pregnancy test (if appropriate)

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INTRODUCTION

What is the purpose of this trial?

This is a trial of a vaccine that is being developed against Nipah virus. Nipah virus is a potentially fatal infection that can cause severe breathing problems and abnormalities with the nervous system. 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 or even pandemics. Currently, 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. The first part of this trial, which took place in 2024, was the first time the vaccine was given to humans. Since then approximately 300 people are estimated to have received the ChAdOx1 NipahB vaccine in the UK and in a trial in Bangladesh.

The purpose of the this new part of the study, which we are calling "cohort 4", is mainly to collect plasma (the liquid part of blood) from participants. Plasma contains antibodies, which are produced by the body after vaccination and can help block viruses. Studying this plasma will help us understand how the vaccine might protect against infection. **This may involve using the plasma in animal studies that have been assessed and approved by an independent ethical review committee** (further details in Samples for animal studies page 20)**.**

How is the trial going to work?

Recruitment and eligibility screening

We plan to recruit an additional 20 people aged between 18 and 55 years to take part in this study at Oxford Vaccine Group, this is in addition to 61 participants who have already been recruited to earlier parts of the trial. Initially, participants will be screened for eligibility with an online questionnaire. This may be followed up with a phone call from the study team. After this, individuals will be invited for an in-person medical assessment by the study medical staff. Eligible participants will then either be invited to attend the first vaccination visit, or attend the pre-vaccination plasma donation visit.

Allocation to a study group

Cohort 4: The additional 20 people that are being recruited to the trial will know at the start of the trial that they are receiving two doses of the ChAdOx1 NipahB vaccine 12 weeks apart.

Follow up

Participants in the group that is currently being recruited (cohort 4) will be followed up for up to 7 months. Participants in cohort 4 will attend one screening visit, two vaccination visits, two or three plasma donation visits and three follow up visits. The trial visit timeline is shown on page 2.

All visits will include a blood test (or plasma donation). In addition to visits, participants will be asked to complete an electronic symptom diary for the first 28 days after each vaccine dose.

Who is sponsoring, organising and funding the research?

The study is organised and sponsored by the University of Oxford. The study is funded by Coalition for Epidemic Preparedness Innovations (CEPI), an international foundation that has been set up to fund research into vaccines and treatments against emerging infectious diseases.

Length of your participation in the study

If you are eligible to take part, we will enrol you into the study for 6 or 7 months depending on whether you are selected for the pre-vaccination plasma donation visit. You may also decide to withdraw from the study early (What will happen if I don't want to carry on with the trial? page 19).

Can I take part?

You must-

Be aged between **18 to 55 years** at the time of your screening visit
Be **in good health** without a history of serious ongoing medical conditions
Be able and willing to **comply with all study requirements** including attending all follow up visits
Be willing to **allow your past medical history to be checked by the study team** (either by allowing us to discuss your medical history with your GP, or by giving us a medical history summary) and be willing for your GP to be notified of your participation in the study
Be willing to provide your **national insurance number or passport number** to be registered on The Over-volunteering Prevention System (TOPS)
Agree to **refrain from blood or blood product donation** during the study (apart from the donations given as part of the study)
Tell us about any **vaccinations** you may have received recently or expect to receive soon
***For females who could potentially become pregnant*: Use effective contraception **30 days prior to the first vaccination and until completion of the study** *and* have a **negative pregnancy test** at the screening visit and vaccination visits
Weigh at least 50 kg

You must NOT have-

Blood/Plasma Donor Ineligibility
Previously been told that you are permanently **not eligible to donate blood or plasma**
Had **significant problems when giving blood or plasma before**

Veins in your arms that are not suitable for this procedure, as judged by the study doctor or nurse - for example, **if people have often struggled to take blood from you in the past because a suitable vein could not be found**
Previously **injected non-prescribed drugs, including recreational drugs, cosmetics, or tanning agents** at any point
A history of **hepatitis B**, **hepatitis C**, **HIV, HTLV or syphilis infection**
Within the last 3 months, the following applied to you **sex with someone who has or may have HIV, hepatitis B, hepatitis C, HTLV or syphilis; sex with someone who has ever injected non-prescribed drugs or received money or drugs for sex; anal sex with a new partner; anal sex with more than one partner; you have taken PrEP or PEP for HIV prevention**
Any other criteria that means you are **ineligible to donate blood or plasma** such as **a new tattoo, piercing, acupuncture, cosmetic skin-piercing procedures in the previous 4 months**
Current and Past Medical Problems
Ever received a dose of the Oxford–AstraZeneca COVID-19 vaccine? It may also have been called the AstraZeneca COVID-19 vaccine, Vaxzevria, ChAdOx1-S or Covishield.
Ever received another ChAdOx1 vaccine (for example in a clinical trial)
A **serious illness**
Any confirmed or suspected **immunosuppressive or immunodeficient state**, including HIV infection, asplenia, severe infection(s)
Received **immunosuppressive therapy** such as **anti-cancer chemotherapy or radiation therapy** within the preceding 12 months, or taken **long-term systemic corticosteroid therapy** (including for more than 7 consecutive days within the previous 3 months)
Had a **severe allergic reaction to a vaccine,** including **anaphylaxis and hypersensitivity**
A history of allergic disease or reactions likely to be exacerbated by any **component of the vaccine** (**EDTA or magnesium chloride**)
Hereditary angioedema, acquired angioedema, or idiopathic angioedema
Had a history of a **major blood clot**, **blood clotting disorder**, or **bleeding disorder**
Had **thrombosis with thrombocytopenia syndrome** (TTS)
Had **capillary leak syndrome**
A history of **cancer** except **basal cell carcinoma** of the skin and **cervical carcinoma in situ**
A **serious ongoing mental health condition** if this may affect your participation in the study
An intake of more than **14 units of alcohol per week** on average (The NHS recommends the following calculator: https://alcoholchange.org.uk/alcohol-facts/interactive-tools/unit-calculator)
A history of a **blood transfusion** or **immunoglobulin infusions** within 3 months before the planned administration of the trial vaccine
A history of **Nipah infection**
Participated in another **Nipah vaccine trial**
Other Vaccines
• You cannot have received an Oxford/AstraZeneca or Janssen COVID-19 vaccine (or any other adenoviral vectored vaccine) within the preceding year.

• You can receive **flu or other COVID-19 vaccines (such as mRNA COVID-19 vaccines) unless this is within 14 days** (before or after) of each study vaccine. This extends to **30 days for any other vaccine**. • You must also be willing to inform the study team if you are offered or receive any **COVID-19 vaccine** during the study.
Other Clinical Trials
You must NOT participate in **another clinical trial** that involves receiving a drug or vaccine in the **12 weeks before the study** starts and for the duration of the study
(In applicable females only) Pregnancy/Breastfeeding During the Study
You must NOT be pregnant or breastfeeding during the study

If you are unclear whether you might eligible to be involved in the study, you can contact the study team (details on page 25) who will be very happy to advise you. The criteria above will be discussed with you in detail at the screening visit by a study doctor to make sure that you are eligible to take part.

As part of assessing your eligibility to take part in the trial (including plasma donation), we will need ask some personal questions that cover areas that you may find sensitive such as recent sexual history or drug use (as outlined in Plasma Donor safety check and sensitive questions page 12).

What is the vaccine being tested?

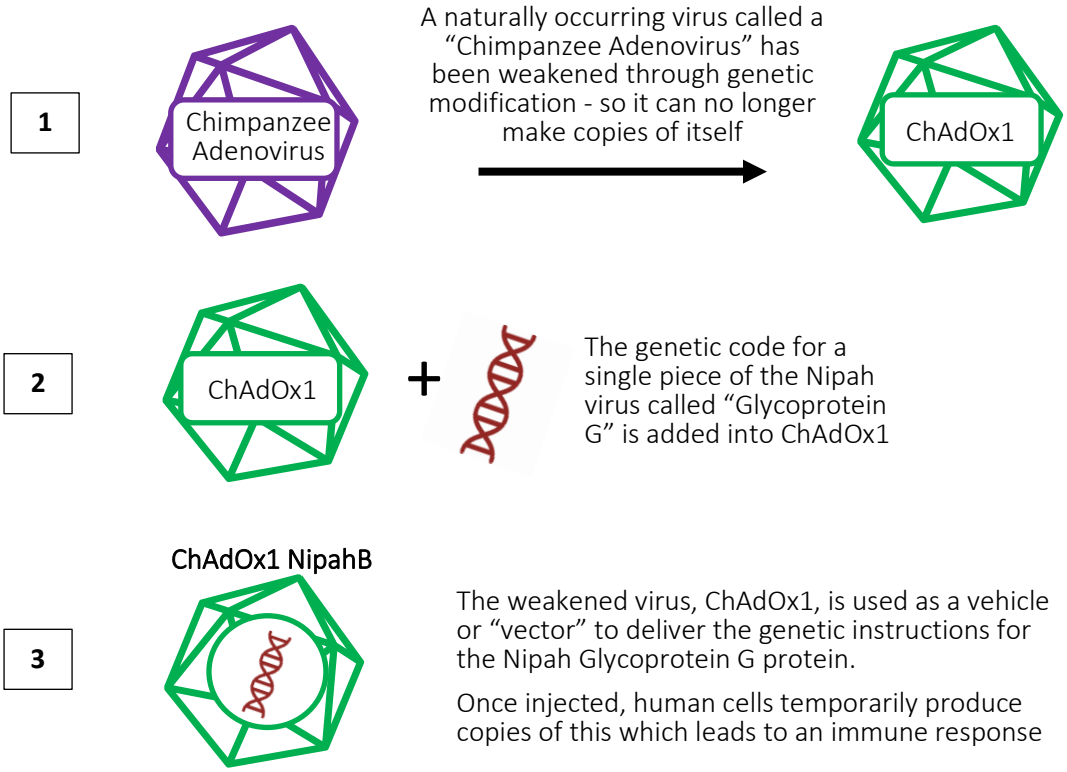
ChAdOx1 NipahB consists of a weakened version of a virus called a *chimpanzee adenovirus.* Chimpanzee adenoviruses are naturally occurring viruses that are completely unrelated to the Nipah virus. The natural, unmodified versions of chimpanzee adenoviruses can cause mild cold/flu-like symptoms in chimpanzees.

We have developed a profoundly weakened version of a chimpanzee adenovirus through genetic engineering. This modified version of the virus is completely unable to reproduce inside the human body. This means it cannot copy itself in humans and it cannot cause infections or be spread from person to person. We call this modified virus 'ChAdOx1' which stands for 'Chimpanzee Adenovirus Oxford 1'.

We then took the weakened virus and inserted a single gene from the Nipah virus. This gene provides the instructions for an important component of the Nipah virus called 'Glycoprotein G'. Nipah Glycoprotein G is used by Nipah virus to invade cells and cause infection. We want to investigate whether people who are vaccinated with ChAdOx1 NipahB will make an immune response against the this.

The genetic code for Nipah Glycoprotein G is the only component of Nipah in the vaccine. Nipah virus itself is not used to manufacture the ChAdOx1 NipahB vaccine so there is no chance of being exposed to Nipah virus at any point during this study. You cannot catch Nipah from the vaccine.

This ChAdOx1 vaccine technology used in the Nipah vaccine in this clinical trial is the same as that used to make the Oxford/AstraZeneca COVID-19 vaccine.



As part of its manufacture, ChAdOx1 is grown in a lab using modified cells that were originally derived from a sample of human tissue. These cells are called HEK 293 (human embryonic kidney 293) cells. More information on the use of human-derived cell lines in the manufacture of vaccine is available at https://vaccineknowledge.ox.ac.uk/vaccine-ingredients#Human-Cell-Lines

What doses of vaccine are used in this trial?

The dose was chosen based on experience with similar vaccines, and is equivalent to the approved dose that is used for the Oxford/AstraZeneca COVID-19 vaccine.

All participants in cohort 4 will receive two doses of the ChAdOx1 NipahB vaccine and will be told this in advance. There will be no "blinding" for this part of the trial.

Previous experience with other ChAdOx1-based vaccines

Although ChAdOx1 NipahB is still in early development, there is now a lot of experience with other ChAdOx1-based vaccines in humans.

Oxford/AstraZeneca COVID-19 vaccine

The Oxford/AstraZeneca COVID-19 vaccine is made using the same ChAdOx1 virus technology that is used for ChAdOx1 Nipah. This has been shown to be safe for the vast majority of individuals and highly effective at protecting against severe COVID-19. However, following administration of the vaccine to millions of people, a very rare but serious side-effect of blood clots in combination with low platelets has now been associated with the vaccine. It is currently unknown why this vaccine appears to lead to

this clotting disorder. Further details of this are included in this information sheet (Are there any risks from taking part in the trial? page 14).

Other ChAdOx1 vaccines

Our research institute has also carried out trials of ChAdOx1 based vaccines against many other diseases such as flu, malaria, meningitis B, TB, HIV and Zika virus. Over 500 individuals have received these other ChAdOx1 vaccine (not including the Oxford/AstraZeneca COVID-19 vaccine). The other ChAdOx1 vaccines were shown to be safe across these trials. They were also able to create strong immune responses against the viruses, bacteria or parasites being targeted.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Your decision will not result in any penalty, or changes to your standard medical care. If you do decide to take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form.

What will happen if I decide to take part?

Online pre-screening questionnaire

If you decide that you would like to take part, we will ask you to complete a short set of online questions that cover some of the key criteria for participation in the trial. We will ask for your consent to access your medical and vaccination records from your GP or NHS database to assess whether you are eligible for the trial. This information will be kept confidential. If you are suitable at this point, we will contact you to provide further instructions on the next steps.

Pre-screening phone-call

If you appear suitable from the pre-screening questionnaire, a member of the study team may contact you by telephone to discuss the study and answer any questions you may have. We will then book you in for an in-person screening visit.

Screening visit

At the screening visit you will meet the study staff who will go through this information sheet and answer any questions you have about the trial. If you decide to take part, and the study team are happy that you have understood the trial information, you will be asked to sign the study consent form.

This will be followed by a physical examination which will involve the doctor listening to your heart and lungs with a stethoscope and examining your abdomen. Your vital signs (blood pressure, pulse, temperature), height and weight will also be measured, and blood samples will be taken. If applicable, a urine sample may also be taken to perform a pregnancy test.

This may take place up to 3 months before the vaccination day. This and other study visits (except for the plasma donation visits) will take place at the Oxford Vaccine Group.

Vaccination visits

If you are eligible to be in the trial after the screening, we will arrange for you to receive the first dose of the study vaccine. You will be asked a few questions to check there have been no new problems since your screening visit. Your blood pressure, pulse and temperature (vital signs) will be checked, and a blood test taken. If appropriate, you will have a urinary pregnancy test before vaccination.

The vaccine will then be given as an injection into your (non-dominant) upper arm. We will temporarily cover the vaccine site with a dressing. We will need to keep an eye on you in a waiting area for at least 30 minutes after the vaccine. After this period the injection site will be inspected. The second vaccination visit (after three months) will also follow the same steps as above. Overall, the vaccination visits will each take about two hours.

Plasma Donation visits

As part of this study, we will ask you to donate plasma (the straw-coloured liquid part of blood). Plasma contains antibodies made after vaccination. Studying these antibodies helps us understand how the vaccine might protect against infection. Some of this work may involve using donated plasma in laboratory tests and/or in animal studies that have been reviewed and approved by an independent ethics committee.

Plasma donation will be performed at a blood donation centre. Plasma donation is similar to blood donation, but there are some differences. Plasma will be collected at a blood donor centre using a special machine. During the procedure, blood is taken from your arm through a needle. The blood is then separated out into components in the machine, which allows the plasma to be collected while the rest of your blood (red cells, white cells and platelets) is returned to you through the same line. Using this technique, up to approximately 800ml of plasma (depending on a person's sex, height, and weight) can be safely collected at each donation. You may be asked to donate plasma two or three times during the study. The amount collected and the time between donations are within the usual limits used for routine plasma donation in the UK.

Plasma donation that is routinely performed on healthy donors in the UK, with over 100,000 donations taking place in England in 2024. A discussion of potential risks of plasma donation is included on page 17.

What to expect:

- The donation procedure may last for around **45 minutes** (and the visit itself may take around **1.5 to 2 hours** as it will include checks before and after the donation).
- When you arrive, staff will confirm that you are eligible to donate that day (including completing the donor safety check.
- A member of staff will clean the skin and place a needle into a vein in your arm. A small plastic tube (a cannula) will sit in the vein during the donation and connect via tubing to the apheresis machine.
- You will be seated throughout and staff will monitor you during the donation. If you feel unwell at any point, tell the staff straight away.
- The donation can take around 45 minutes. You are free to browse your phone, read a book or similar during this time.

This short video produced by NHS Blood Donation describes what to expect during a typical plasma donation. Accessible by QR code below:

What to expect during a plasma donation | NHS Give Blood

[[URL: https://youtu.be/LGtQ6o3mGbM]]

Preparing for your plasma donation visits

On the day:

- Drink plenty of fluids to stay well hydrated
- Eat a nutritious meal
- **Avoid fatty foods in the 24 hours before your donation** (as this can affect the quality of your plasma).
- Choose clothing with loose sleeves that can be rolled up easily

After the visit:

- Stay hydrated.
- Avoid strenuous exercise for the rest of the day. Light exercise is fine, although you should make sure you are fully recovered first.

Plasma Donor safety check and sensitive questions

As part of the screening visit and plasma donation visit you will be asked to complete a donor safety check. This will involve being asked questions about potentially sensitive personal details (for example about past infections, sexual history, travel, and drug use). These questions are asked to protect your safety and the safety of any potential recipient of the donated plasma, and your answers are treated as strictly confidential (as described on page 21).

Sometimes healthy people are temporarily or permanently unable to donate plasma (for example because of travel, recent illness, a low blood test result, or difficulty with veins). If this happens, the study team will discuss what it means for your participation in the trial.

Electronic symptom diary 'eDiary' *(to be completed at home)*

During the vaccination visits you will be given access to an online symptom eDiary via an email link sent to your email address. We will ask you to record any symptoms or illnesses you experience in the 28 days following each vaccine, even if you think these are unrelated. For the first 7 days we will also ask you to measure and record your temperature each evening using an oral thermometer that we will provide. We will also give you a tape measure so that if you experience any redness around the injection site you have something to measure this with (see Vaccine Reactions around the injection site – local reactions page 14).

Follow up visits

After you have received the vaccination, you will attend the clinic for several short follow up visits, as indicated in the trial visit timeline, up to 7 months after receiving the first vaccine (cohort 4) The visits are to check if you are experiencing any problems after the vaccine, review your injection site, check your eDiary and have a blood test. During the course of the trial, you may also be asked to attend for an extra visit, for example, if a blood test needs to be repeated.

Considerations before taking part in this study

Other vaccinations or medications during the study

If during the trial you require any vaccinations for health, travel, or occupational reasons, you should inform the study team beforehand. We ask you not to receive any vaccines within 30 days (before and after) of receiving each study vaccine EXCEPT for flu and COVID-19 vaccines which you may not receive within 14 days of each study vaccine.

If you begin taking any new medications (prescribed or over the counter) during the study, please make a note of these and inform the study team.

You must not take paracetamol, ibuprofen or other similar medications used for treating fevers in the 4-hour period before receiving each dose of vaccine.

COVID-19

You will be required to follow any local COVID-19 guidelines that are in place at the study location during your visits. This may include being asked to wear a face mask during your visits and other measures.

If you develop a suspected flu-like illness near to a planned study visit, please contact the study team before attending.

Private insurance

If you have private medical insurance or travel insurance, participation in a trial will often not affect your cover for any conditions unrelated to the trial, but to be certain you must tell your insurer you are planning to participate.

Contraception

There is no data on the use of this vaccine in pregnancy. We therefore require volunteers who could become pregnant to use contraception to participate (exceptions to this are below).

Female participants where any of the following apply will not be required to use contraception:

- Post-menopausal
- Surgical sterilisation
- Complete abstinence from sex with a male partner

Acceptable effective contraception methods include:

- Oral, injected or implanted hormonal contraceptives
- Intrauterine device (IUD) intrauterine system (IUS)
- Condoms or occlusive cap with spermicide
- Sole sexual partner is a vasectomised male

Male participants in the trial are not required to use barrier contraception methods for the purposes of contraception. There is no evidence that the vaccine can be shed into semen.

Pregnancy

If you were to become pregnant during the trial, you should tell us immediately so that we can review certain trial procedures such as blood sampling. With your consent we would continue to follow you up for safety reasons but you will not be given any further vaccine as part of the trial. Volunteers who could become pregnant will also be asked to complete a pregnancy test at the final follow up visit.

What should I avoid during the trial?

Blood donation

Under current UK regulations, participants have to refrain from blood donation during their involvement in the study. However, you will be able to restart blood donation once your last study visit has been completed.

Taking part in other clinical trials

You should not take part in other clinical trials where drugs or vaccines are administered during this study. You should also not take part in studies that involve repeated blood sampling at the same time as this trial.

Are there any risks from the ChAdOx1 NipahB vaccine?

We can predict, from past experience with other ChAdOx1 vaccines, what the symptoms should be like with this new vaccine. However, it is important to remember this vaccine is in a very early stage of development and has not been tested in humans before. For this reason, there is a chance you could experience an unexpectedly severe side effect or a new side effect that has not been seen before. Potential risks are summarised below:

Vaccine site 'local' reactions

As with any vaccine, you may experience some 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 although may occasionally persist up to a week or even longer.

Other less common but possible symptoms around the injection site might include redness, swelling, itchiness or a feeling of warmth.

General reactions

During the first 24-48 hours after vaccination you may experience flu-like symptoms such as muscle aches, joint aches, feverishness, chills, headache, nausea, tiredness and feeling generally unwell. We would expect these symptoms to resolve within a few days.

How common were reactions in other clinical trials using ChAdOx1 based vaccines?

Vaccine reaction symptoms were measured in volunteers in the large Oxford/AstraZeneca COVID-19 vaccine trials involving over 10,000 volunteers. The percentage of volunteers experiencing symptoms after vaccination is shown below. Symptoms were mostly described by volunteers as mild, although a minority described temporary moderate or severe-intensity symptoms. The dose given to those individuals is equivalent to the dose we plan to use in this trial (What doses of vaccine are used in this trial? page 9).

Percentage of participants reporting side effects in trials of the Oxford/AstraZeneca COVID-19 vaccine	
Vaccine site reactions	**General reactions**
Vaccination site tenderness (68%)	Fatigue (53%)
Vaccination arm pain (58%)	Headaches (53%)
	Feeling generally unwell (44%)
	Muscle aches (44%)
	Feeling feverish (34%)
	Joint pains (27%)
	Nausea (22%)
	Fever 38°C and over (8%)

An analysis of symptoms following the Oxford/AstraZeneca COVID-19 vaccine by the UK's medical regulator, the MHRA, has shown that individuals tend to have fewer and milder symptoms after their second dose.

The other ChAdOx1 vaccines that have been used in smaller clinical trials had similar rates of side effects when used at the equivalent dose.

Post-vaccination symptoms completely resolved within a few days in the vast majority of people in all previous ChAdOx1 trials.

Serious rare blood clot disorder with similar vaccines

The Oxford/AstraZeneca COVID-19 vaccine has been associated with a very rare but serious blood clot condition that can lead to death or serious long-term disability. The condition consists of unusual types of blood clots together with low levels of platelets in the blood (thrombosis with thrombocytopenia syndrome). Most of the clots were a rare brain blood clot known as a 'cerebral venous sinus thrombosis'. Unusual blood clots occurring in other organs along with low blood platelets were also reported. The majority of these cases occurred within the first 3 weeks after vaccination.

This condition is not predictable and has occurred in previously healthy people, although it appears slightly less common in older people. According to The Lancet Global Health published data approximately 10 cases were reported of TTS (thrombosis with thrombocytopenia syndrome) within 21 days of AZD1222 vaccination per million doses in the UK, that is 1 in approximately 100,000 doses of vaccination. Approximately 1 in 5 patients who develop this condition unfortunately die.
Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have also been reported very rarely, usually within the first four weeks following vaccination with the Oxford/AstraZeneca COVID-19 vaccine.

We do not know whether these rare reactions may also occur with other ChAdOx1 vaccines, such as the ChAdOx1 NipahB vaccine used in this study. We therefore advise you to seek urgent medical advice from the study team if you experience the following, especially in the first 28 days after each of your trial vaccines:

- Sudden severe headache that does not improve with usual painkillers or is getting worse

- An unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness or seizures
- New and unexplained pinprick bruising or bleeding
- Shortness of breath, chest pain, leg swelling or persistent abdominal pain

You will be provided with a medic alert card with a 24-hour study mobile number. If you experience any of the above events or are in any way concerned, you can use this to contact the study doctors at any time. We advise you to carry the medic alert card with you throughout the trial and you may use this to show medical staff that you are taking part in this study.

Other serious vaccine reactions

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with the Oxford/AstraZeneca COVID-19 vaccine. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek immediate medical attention from the study team if you develop these symptoms following vaccination.

Nervous system reactions are also extremely rare but have been reported with vaccinations in the past. Guillain-Barré syndrome (GBS) and transverse myelitis are very rare conditions in which people can develop severe weakness. Cases of GBS and transverse myelitis have been reported after COVID-19 vaccinations and the UK MHRA have updated their information to list GBS as a possible very rare side effect of the Oxford/AstraZeneca COVID-19 vaccine.

Severe allergic reactions to vaccines (anaphylaxis) are rare but can be fatal. In case of this unlikely event, medication for treating allergic reactions is kept in the clinic room and the study team are appropriately trained in the management of anaphylaxis.

Unknown/unexpected side effects

With any new medicine or vaccine that is in early development there is always a possibility of an unpredicted or unexpected side effect occurring. This could include something severe. If you experience concerning or unexpected symptoms, you should phone the 24-hour study contact number and speak to a study doctor.

Potential interaction with adenovirus-based vaccines (such as the Oxford/AstraZeneca COVID-19 and Janssen COVID-19 vaccines)

When people are vaccinated with ChAdOx1 NipahB they should develop the intended immune response against Nipah Glycoprotein G. However, they may develop an immune response against ChAdOx1 itself. Some scientists believe that having a strong immune response against ChAdOx1 might interfere with future doses of ChAdOx1-based vaccines and prevent them working as well. The same potential interference issue might also apply to other related (adenoviral) vaccines (e.g. the Janssen COVID-19 vaccine), although these are not currently in widespread use in the UK. This is the reason we are not including participants who have had an adenoviral-vaccine within the year prior to the trial.

Are there any other potential risks from taking part in the trial?

Plasma Donation – potential risks

Plasma donation using an "apheresis" machine is a routine way of collecting plasma from healthy donors in the UK. Most people have no symptoms or only minor symptoms. The most common issues are:

- Bruising where the needle (cannula) was placed
- Arm discomfort during or after the donation
- Feeling light-headed or faint
- A mild reaction to the anti-coagulant in the apheresis machine. In some people this can cause temporary symptoms such as tingling around the lips or fingers, a metallic taste, feeling cold or shivery, or mild nausea. These symptoms are usually mild and settle quickly. If you notice any of these symptoms during the donation, tell the staff straight away - they can slow the machine and manage the symptoms.
- Occasionally the donation may need to be stopped early if the plasma appears "milky" due to a high fat level in the blood (lipaemia).

Less common risks relate to placing the needle (cannula) into a vein. These can include re-bleeding or local inflammation at the needle site, scarring, tendon injury, temporary or permanent nerve injury, and accidental arterial puncture. Staff are trained to keep you safe and give immediate treatment if needed.

Other possible risks include:

- Iron deficiency (you could lose up to 200-250 mg of iron) - your haemoglobin level is checked before you donate
- Allergic reactions to the dressing or skin cleaning solution (chlorhexidine) - usually mild, very occasionally severe (anaphylaxis)
- Protein loss - protein levels drop after donation; the main symptom of low protein is swelling (especially in the legs)

Other extremely rare complications can include a blood clot in the arm (DVT), haemolysis (breakdown of red blood cells in the machine), air entering the bloodstream (air embolism), or serious cardiovascular events such as heart attack or stroke. The following table summarises how common these side effects and complications are:

Frequency	**Possible complications**
Common (1 in 10 – 1 in 100)	Feeling faint, bruising
Uncommon (1 in 100 – 1 in 1,000)	Fainting, arm pain, re-bleeding, local inflammation
Rare (1 in 1,000 – 1 in 10,000)	Nerve injury, nerve irritation, arterial puncture
Very rare (1 in 10,000 – 1 in 100,000)	Allergic reaction, tendon injury
Extremely rare (1 in 1,000,000)	Deep vein thrombosis (DVT), anaphylaxis, thrombophlebitis, AV fistula, compartment syndrome, other cardiovascular events

Adapted from Data from NHS Blood and Transplant Donor consent for platelets and plasma donation (INF1572) 14June2021 ("Data from NHSBT Clinical Statistics team 2019/20").

Blood samples

Blood sampling may cause slight pain and sometimes bruising. Occasionally, people feel light-headed, nauseous or faint. We will take around 15 ml at most visits (the equivalent of around 1 tablespoon). This is a fairly small amount of blood and should be well tolerated by healthy adults. The **total** amount of blood samples that we will take over the whole trial period is approximately 70 ml.

These blood samples are separate from the plasma collected during the plasma donation visits, which is described in the Plasma Donation visits section.

Incidental medical findings

As we carry out several medical tests throughout the trial, it is possible that we pick up previously unknown health issues (e.g. high blood pressure, abnormal blood results). If abnormal results or undiagnosed conditions are found during the study, these would be discussed with you and, if you agreed, your GP would also be informed of these results. Sometimes incidental medical findings might require your GP to carry out further investigations such as blood tests, scans or referral to specialists.

In the UK, healthcare professionals are legally obliged to report any new suspected cases of hepatitis B and hepatitis C to the UK Health Security Agency (UKHSA). If you are found to have hepatitis B or C, we will be required to send a report to the UKHSA, including your personal contact information. It's important to note that you cannot opt out of this due to UK reporting requirements. The same applies if we identify any other infection or condition that is legally 'notifiable' in the UK.

What are the advantages of taking part?

You will not gain any direct personal benefit from the trial as you are unlikely to be at immediate risk from Nipah virus. You should not assume you have gained any protection from future Nipah virus infection even if you receive the ChAdOx1 NipahB vaccine within the study.

Will I be paid for taking part in this trial?

Study participants would be reimbursed for their time, travel and inconvenience of taking part in the study. The maximum reimbursement for any participant who completes all study visits is £1020 for those assigned 2 plasma donation visits and £1200 for those assigned 3 plasma doantion visits for cohort 4. All participants will be reimbursed based on the following figures:

- Travel expenses: £30 per visit
- Inconvenience of blood tests/sample collection: £20 per blood donation
- Time required for visits: £60 per screening or vaccination visit, £40 per follow-up visit
- Plasma donation visits: £180 per visit
- Diary card completion: £30 per fully completed diary card

The sum reimbursed is on a pro-rata basis, so, if for example, you choose to withdraw halfway through the study, we would calculate your reimbursement based on the visits you have attended and samples that have been obtained.

Reimbursements to participants in cohort 4 will be made following the vaccination visit, and after visits 4, 7 and 8.

We require participants to provide their bank details at screening. Bank details are kept confidential. Personal information such as your name, bank details and national insurance number may be shared

with the University finance team to process or verify your reimbursement payments. Financial auditors may also audit the records where this information is held. All confidential data will be stored according to the UK General Data Protection Regulation (see below).

Your bank details will be stored securely for 7 years in accordance with University of Oxford Financial policy.

You may also receive reimbursement for any unscheduled visits you attend. You would be reimbursed £90 per unscheduled visit.

We will not pay tax or National Insurance from the money due to you. It is your responsibility to pay these and to check how any compensation received from taking part in the study affects any state benefits to which you are entitled. Contact HM Revenue & Customs for information (http://www.hmrc.gov.uk/ or telephone 0300 200 3300).

What if new information becomes available?

Sometimes during the course of a trial, new information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the study. If you decide to continue to take part, you will be asked to sign an updated consent form. On receiving new information, we may consider it to be in your best interests to withdraw you from the study.

If any new information or safety concerns arise during the trial in relation to ChAdOx1, this will be reviewed, and you would be kept fully updated.

What happens if I don't want to carry on with the trial?

At any time during the study you are entirely free to change your mind about taking part, and to withdraw from the study. This would not result in any penalty. We would use the samples and data we have collected from you in our analysis of the study up until the point you informed us that you wanted to withdraw. You are free to request that your samples are destroyed at any time during or after the study (if they haven't yet been analysed).

In exceptional circumstances, your participation in the study might also be stopped early by the study doctor or the sponsor of the trial.

What will happen to any samples I give during the trial?

The blood and urine samples collected during this study will be analysed in the Oxford Vaccine Group and University of Oxford research laboratories and NHS laboratories. Samples may be sent to other research facilities (including outside of the UK which may include shipments to *National Emerging Infectious Diseases Laboratories* (*NEIDL*), USA; *Translational Health Science and Technology Institute (THSTI*), India; International Centre for Diarrhoeal Disease Research, Bangladesh; amongst other facilities) for further testing or processing.

Clinical safety blood samples are sent to local NHS laboratories and follow local sample labelling requirements (which may include personal identifiers). As part of processing clinical safety blood samples, local NHS laboratories may be required to add the results to your medical records. Samples may need to be sent to other specialist laboratories for additional clinical tests if required.

Samples sent to research laboratories for processing, within and outside of the UK, will not have personal identifiers (they will be identified by study number and participant number only).

However, as your DNA is unique, samples can never be completely anonymous.

The following tests will be performed on your samples:

- Blood tests of for blood cell counts and liver and kidney function.
- Tests for Hepatitis B, Hepatitis C, HIV, Hepatitis E, HTLV, and syphilis (at the screening visit, and on plasma samples). Further testing may also be required as part of the plasma donation eligibility testing (including malaria, CMV, hepatitis A, Human B18, West Nile virus, Chagas, and others if required).
- HLA typing, a genetic test of components of the body's immune system.
- Tests of immune responses following vaccination looking at your antibodies and immune cells.
- Plasma samples (or other samples) may be shipped internationally to other research centres for analysis, processing, or for other reasons to support the development of this vaccine or other vaccines, or development of assays related to Nipah virus or other viruses. Additionally, samples may be used for animal research (see Samples for animal studies page 20).
- Urine pregnancy testing (if applicable).
- Blood samples taken in this study may be used for research involving the creation of specific antibodies called 'monoclonal antibodies'.

Using remaining samples in the future

If you choose to take part in this study, you will be asked if you agree for any remaining samples to be stored and used in future research. You will not be asked to donate any extra samples or undergo any extra procedures. All samples will be stored with a code, instead of information that would identify you directly.

Samples for animal studies

Samples from this study may be used in animal studies to help understand how well vaccine-induced antibodies might protect against Nipah virus. Any animal study using samples from this trial would be reviewed and approved in advance by an independent ethics committee and carried out only at licensed facilities, in the UK or overseas, under the relevant local laws and animal welfare standards. At present, we expect that plasma from this study will be used in an animal study outside the UK at an academic facility in the USA, and this work is expected to involve non-human primates. Further animal studies may be needed at other sites if there is a clear scientific reason, for example if requested by a regulator.

Will any genetic tests be done?

We will do genetic tests on your blood samples to look at the patterns of genes that regulate your own individual immune response. These are called Human Leukocyte Antigen (HLA) genes. This will help us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We may also try to identify and study the genes that appear to be important in your immune response to the vaccination. You will not receive the results of any genetic tests performed.

What if something goes wrong?

If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions. We will provide compensation for any injury caused by taking part in this study. We will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol
- Any test or procedure you received as part of the trial

Any payment would be without legal commitment. (Please ask if you wish more information on this). We would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the trial protocol or where the protocol wasn't followed.

Complaint's statement

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the research investigators at info@ovg.ox.ac.uk. Alternatively, you may contact the sponsor organisation of this study (University of Oxford) at the Research Governance, Ethics and Assurance (RGEA) team office on 01865 616480 or email rgea.complaints@admin.ox.ac.uk

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

Would my taking part in this trial be kept confidential?

All information that is collected about you during the research will be kept strictly confidential. Apart from clinical samples (as outlined above) any information about you that leaves the clinic would have your name and address removed so that you could not be recognised, except for letters sent to your own GP. In order to enrol into this study, you are required to consent for us to contact your GP.

We will write to your GP to inform them about your enrolment and study completion status, so they can update your medical records accordingly. Your GP will also be asked to share information about your medical history and give access to any other medical records as required to ensure there are no medical reasons that would prevent you from taking part. We would only notify your GP of the results of any medical tests with your permission.

Responsible members of the University of Oxford, the relevant NHS Trusts involved in the research and the regulatory agency responsible for clinical trials in the UK, the MHRA, may also be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. No one else will be told that you are involved in the study.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you, from your medical records/your GP and/or hospital records for this research project. We will share your information related to this research project with the following types of organisations:

- Local NHS laboratories as part of processing the clinical safety blood samples.
- United Kingdom Health Security Agency (UKHSA) (please see page 18)

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information will include your initials, NHS number, name, contact details/home address and email address.

People will use this information to do the research or to check your records to make sure that the research is being done properly. Responsible members of the University of Oxford, regulatory authorities Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure by the following methods:

- Data will be collected and held by the Oxford Vaccine Group. It will be accessible to staff at the Oxford Vaccine Group, and responsible staff from the University of Oxford who may monitor/audit the data collection process.
- The University of Oxford Data Management and IT Team will be able to view your email address, which is necessary for the e-diary to function.
- Storing all data in secure servers held by the University of Oxford.

International Transfers

We may share data about you outside the UK for research related purposes to be analysed by collaborating research groups. If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

Study funder/vaccine manufacturer and collaborating laboratories.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules https://ico.org.uk/for-organisations/report-a-breach.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of 25 years in line with the Clinical Trials Regulations. Once the retention period has finished, the study data will be kept in a way that does not identify you.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do that research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team [info@ovg.ox.ac.uk]
- sending an email to [info@ovg.ox.ac.uk]
- calling us on [01865 611400]
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: https://www.ox.ac.uk/about/how-we-are-run/policies-and-statements/policy-hub/data-protection-policy

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/.

TOPS database registration

Volunteers participating in this study must not be enrolled in another study that involves receiving investigational medications or vaccines at the same time. In order to check this, you will be asked to provide your national insurance or passport number. Details will be entered on to a national database, called 'The Over-Volunteering Prevention System' (TOPS), which helps prevent volunteers from taking part in too many clinical trials. These details will also be stored at the study location for the duration of the study. Only staff at the Oxford Vaccine Group and other medicines research units can access the TOPS database. If you receive a dose of the study vaccine, this data will be retained in TOPS. If you do not receive a dose, the record will state this, and your data will be retained in TOPS for two years.

What will happen to the results of the research study?

The results of this research study may be presented at scientific meetings or conferences and published in a scientific medical journal. This can take approximately 2 years after the study is completed. Your individual results would not be identifiable nor would you be identified in any report or publication. If you contact the researchers in the future, you can obtain a copy of the results.

The de-identified research data from this study will be shared with the collaborating partners who are organising and funding this research work. Data from this study may be used to file patents or licence

vaccines in the future or make profits in other ways. You would not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example a MD or PhD.

Who has reviewed the study?

This research has been looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central - Oxford A Research Ethics Committee. The Oxford Vaccine Centre Patient Public Involvement group have reviewed the main participant-facing documents associated with this trial (Participant Information sheet, Consent form, and advertising materials).

The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the study design and has granted permission to use this unlicensed vaccine in this clinical study.

Further information and contact details

We hope this information sheet has given you enough information to make decision on whether to volunteer for this study. If you would like further information about participating in research, please visit the following website: https://www.nhs.uk/conditions/clinical-trials/

For independent advice about participating in this trial, you may wish to contact your GP.

If you are interested in taking part in this study then please complete the online pre-screening questionnaire at: https://www.ovg.ox.ac.uk/studies/niv

If you have further questions about the trial that you would like to discuss with our team, please contact us at:

Email: info@ovg.ox.ac.uk

Tel: 01865 611400

Oxford Vaccine Group, University of Oxford

Centre for Clinical Vaccinology and Tropical Medicine

Churchill Hospital, Headington, Oxford, OX3 7LE

Thank you for your interest in taking part in this study.