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RATIONALE-15

caRriage to Assess proTectlon Of New pneumococccAL vaccinEs – PCV15

Participant Information Sheet – Nasal Biopsy Group

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Study Group Overview

In this study we want to understand how an approved pneumococcal vaccine generates immunity inside the nose. We will collect nasal tissue biopsies before and after vaccination.



Participants:
Age 18-50
Be in good health



Study length:
70 days



Number of visits:
7 visits at study site



Approximately 4 tablespoons of **blood** taken at each visit. Nasal samples (swabs and washes) will also be taken



3 safety phone calls



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What is this research study about?

You are invited to take part in a research project sponsored by the University of Oxford carried out by the Oxford Vaccine Group.

For this research study we aim to recruit up to **106 people aged 18-50 years** to take part in a study of an approved vaccine against a common bacterium called *Streptococcus pneumoniae* (Spn, pneumococcus) to see how the vaccine increases immunity in the nose and in the blood. The vaccine is called Pneumococcal Conjugate Vaccine 15, PCV15 (VAXNEUVANCE™). Within the 106 people that will take part in this study we will have a **small group of up to 5 participants** that will undergo a different procedure. This participant information sheet describes the relevant information for this small group.

Studying immune responses in the nose is important because you can find pneumococcus in the nose of approx. 1 in 10 healthy adults and children. This harmless state is called “carriage”; and people that have it are just carriers of it, often with no symptoms. However, the bacteria can transmit from a person that is a carrier to other people at risk (the elderly, children and people with health conditions) and can cause disease (e.g., pneumonia).

In this study we want to understand the immune responses in the nose and blood to PCV15. To do this, we want to collect a small tissue sample from the inside of peoples’ nose before and after vaccination.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If anything is not clear or if you would like more information.

Take time to decide whether you wish to take part. Please feel free to consult your doctor or other allied health care professionals if you wish to.



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Who are we?

We are researchers at The University of Oxford (<https://www.ovg.ox.ac.uk/>) and The Liverpool School of Tropical Medicine (LSTM, <https://www.lstmed.ac.uk/LVG>). We have been studying immunity in different infectious diseases looking in particular at what happens in the nose of healthy people (volunteers) for over ten years. Our research is world-leading and we seek to help develop and improve vaccines against pneumococcus and other infections. We have a large amount of experience in running clinical studies and trials like this.

Why is this research study needed?

Pneumococcus causes serious infections such as pneumonia, meningitis and sepsis (severe infection causing inflammation and organ damage) worldwide. The burden of pneumococcal infection is high in low- and middle-income countries with over 1 million deaths per year. Even though there are antibiotics to treat pneumococcus, vaccination remains the primary method for reducing its impact.

Small numbers of pneumococcus are often found in the nose, and approximately 10% of the population carry the bacteria at any one time, which is called nasal carriage. It is more common in children, and usually, the carrier is not aware of it and does not have any symptoms. There is some evidence suggesting nasal carriage triggers your immune system and protects you from future disease.

However, young children, older adults and people with chronic illness are at increased risk of developing an infection after carriage, such as pneumonia, meningitis, or sepsis.

Getting tissue from the inside of the nose (a biopsy) will allow us to study the way the body's immune system responds to the vaccine. Performing a biopsy allows us to collect information about the immune system that cannot be collected by swabs, fluid samples or blood samples.

Our long-term goal is to help develop more protective vaccines against pneumococcus. To do that, we need to gain a better understanding of how pneumococcus behaves and how current



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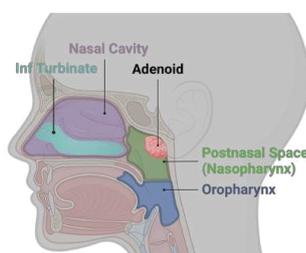


vaccines work. There are over 100 different types (also known as ‘serotypes’) of pneumococcus, and some of the current vaccines protect against 13 (PCV13 vaccine) and 15 (PCV15 vaccine) serotypes. We are interested in a specific serotype of pneumococcus, serotype 3 (Spn3). This is because although it is included in all those vaccines, it continues to be found in the community, causing infections, particularly in young children and the elderly. We are also interested in PCV15 vaccine, a vaccine that is routinely given to babies and that can potentially protect better against this Spn3 serotype of pneumococcus. To try to understand how vaccines work and how we can improve them, we want to study the body’s immune response to PCV15 and see the effect of the vaccine on the carriage of Spn3.

What is a nasal biopsy and what is the vaccine?

Nasal tissue biopsies are procedures in which a trained doctor (ear, nose and throat [ENT] surgeon) takes a small tissue sample from the inside of the nose. These procedures are done in outpatient clinics and use local anaesthetic spray (a medicine that will numb the nose lining so that the person does not feel pain). These procedures are typically used to collect nasal tissue samples to help diagnose infections, inflammatory conditions and even cancer in the nose. For this research study, we will collect a nasal biopsy from an area at the front of the nose called the Inferior Turbinate and/or from an area at the back of the nose called the adenoid or postnasal space.

The figure below shows the location of the Inferior (Inf) Turbinate, which sits in the nasal cavity, and adenoid tonsil tissue, which sits in the Postnasal Space.



The PCV15 **vaccine** is approved and is currently given routinely to babies and older adults in the UK and many other high-and middle-income countries. The PCV15 market name is



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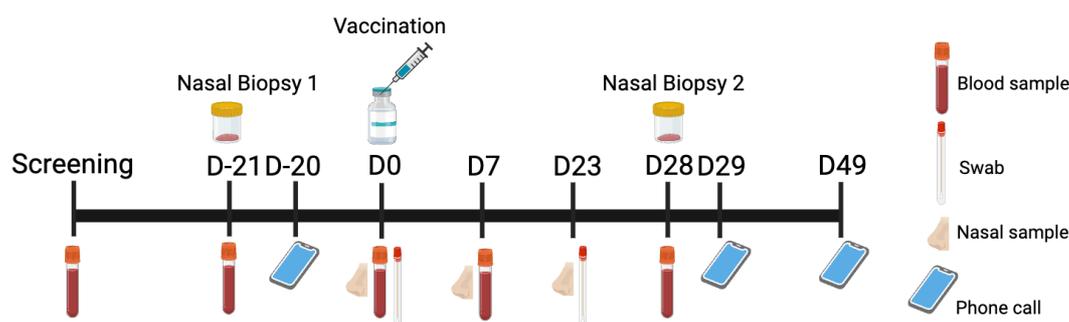


VAXNEUVANCE™. It is an effective vaccine against infections from pneumococcus but more data is needed to understand its protection against carriage.

More information about how vaccines are made is available at
<https://vaccineknowledge.ox.ac.uk/vaccine-ingredients>

What will happen in the study?

All participants will have a nasal biopsy followed by 1 dose of the PCV15 vaccine around 3 weeks later. A second biopsy will be performed around 1 month after the vaccination. The total duration of the study is around 70 days from enrolment. See study timeline below:



We are looking for healthy adults aged 18 – 50 years to take part. People with serious medical conditions or immune system conditions will not be able to take part (the study team will discuss with you examples of such conditions). People that have been vaccinated with a pneumococcal vaccine in the past 5 years or that took part in a human challenge study with Spn in the past 2 years are not eligible as well.

If you are unsure whether you can join the study, you can contact the study team to discuss further. The criteria is available on the online screening questionnaire and will be discussed at the screening visit.

- **Online Screening Questionnaire:** <https://www.ovg.ox.ac.uk/studies/rationale15> to check if you can take part by asking about your medical history and record your contact details.



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This registers your interest in the study and we will ask you to provide your NHS number and consent for the study team to access your medical records through your GP and other NHS databases and record your contact details. Your contact details will be kept secure and confidential (for more information please refer to the confidentiality section below).

- **Screening visit:** You will discuss the study with a member of the clinical team, and you can ask any questions. If you wish to take part, you will be asked to sign a consent form.

Our research staff will confirm your medical and vaccine history, perform a physical examination, check your vital signs, and take blood and nasal samples, and a urine pregnancy test (if applicable). You will need to provide proof of National Insurance Number (UK citizen) or Passport (non-UK citizen) for the team to register you on The Over-volunteering Prevention System (TOPS). This is performed as a standard practice when volunteering in a research study and acts as a safety measure to prevent volunteers taking part in multiple studies that when combined, may negatively impact their health due to drug interactions or having to provide multiple blood samples. This visit will take around 1 hour and a half and will occur at your local study site.

- **Nasal Biopsy visit:** We will collect a nasal biopsy before and after vaccination. Nasal biopsy procedure will be conducted at the Oxford Vaccine Group. During the nasal biopsy visit you will have an examination by an Ear, Nose and Throat (ENT) doctor to explain the procedure to you, assess your eligibility and determine if it is safe to proceed with such a biopsy. If applicable you will have a urine pregnancy test before the biopsy. If you are happy to go ahead, the doctor will numb the inside of your nose with a local anaesthetic spray and apply local anaesthetic on a small piece of specialised surgical cotton-wool which sits in your nose for approximately 10 minutes before the procedure. This has an unpleasant taste but is not painful. Typically, injections of local anaesthetic are not used for biopsies, but if this is needed, you may experience small discomfort for few seconds similar to a mild bee sting. You will remain awake throughout the biopsy and will not be sedated. The doctor may use a small flexible tube with a camera (called nasal endoscope) to look at the back of your nose cavity and then collect a small piece of tissue from one or both areas on the inside of your nose. These samples will be roughly the size of a grain of rice. After the biopsy, the doctor may cover the area with a small dressing which will get absorbed on its own. The doctor may also chemically seal (cauterise) the area where the biopsy was taken. These procedures are not typically painful but some individuals may experience discomfort. You will be observed in the clinic for approximately 30 minutes after



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the biopsy to make sure it is safe for you to go home. The whole visit will last approximately 2 hours.

- **Vaccination visit:** You will be asked about any changes in health since the screening and biopsy visit, check your vital signs and collect blood and nasal samples. If appropriate you will have a urine pregnancy test before the vaccination. The PCV15 vaccine will be given as an injection into the muscle of your non-dominant arm, preferably. The site of the injection will be covered temporarily, and you will be observed for at least 15 minutes to observe for any reactions. This visit will take around 1 hour and a half and will occur at your local study site.
- **The vaccine dose** contains components of 15 serotypes of pneumococcus attached to a protein that improves the immunity generated by the vaccine. Expected symptoms or reactions and possible reactions seen with similar vaccines will be discussed in the section **vaccination related risk**.
- **Follow-up visits:** After the vaccination you will attend the clinic for 2 short follow-up visits. At these visits we will ask about any symptoms or illnesses that you have experienced, and we will take blood, throat swabs and nasal samples. The amount of blood taken can vary according to when the visit is taking place. Approximately 60mls, or 4 tablespoons of blood is taken at each in person visit (approximately 12 tablespoon in total for the study). For comparison, a single donation to the NHS blood bank would be approximately 470ml. The blood is taken to assess the immune responses of the participants to the PCV15 vaccine. We may need to repeat blood tests if anything needs checking. The research team will also phone you on 3 occasions during the study to check how you are feeling after the biopsy procedure.

Are there any risks in taking part in this research?

Vaccine related

PCV15 is a licensed vaccine in the United Kingdom. There is no risk of developing pneumococcal pneumonia or other pneumococcal infection from the vaccine. This vaccine is part of the immunisation programme against pneumococcal disease for children and adults at risk. We will give the vaccine in the same way it is given to babies and the older adults routinely.



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Side effects of the vaccine are as you would expect to see after any vaccine and includes: pain, redness, swelling and itchiness at the site of the injection. These are temporary and will not last for long. **General reactions** including headache, fatigue, muscle aches/pain, joint pain, nausea, vomiting, rash, dizziness, feeling feverish and chills may also be experienced by some participants. Effects can last for a couple of days

Severe allergic reactions (anaphylaxis) to a vaccine are rare but can occur with any vaccine and can be fatal. In the unlikely event of this occurring, medications for treating allergic reactions are kept in the clinic room and the clinical study team are appropriately trained in the management of anaphylaxis.

Nasal Biopsy related

Nasal biopsies are safe and well-tolerated procedures but, as with any medical intervention, they carry some risks:

- **Pain:** The biopsy procedure should not be painful, but you may feel some pressure or tugging in your nose. You may feel some mild discomfort when the anaesthetic is applied. You can take a simple painkiller like paracetamol if you need it; avoid taking aspirin, as this may increase the risk of nosebleeds. Any tenderness or discomfort after the procedure will typically be mild and resolve within 24 hours.
- **Bleeding:** A small amount bleeding after the procedure is common, and this would typically be some mild blood staining to your normal nasal secretions for a few days after the procedure. Continuous nose bleeding is rare, occurring after about 1 in every 100 biopsies, but can happen up to three weeks after the procedure. If you have continuous bleeding from the nose, firmly squeeze the nostrils shut, holding the pressure for 15 minutes, and repeat if needed. If the bleeding does not stop after 30 minutes of pressure, you will need to attend your local hospital emergency department. If there is bleeding, the blood vessels may be sealed with cautery or covered with a nasal dressing, and a telescope may be used to help with this. In very rare cases, participants may need an inflatable nasal pack placed inside the nose to stop the bleeding and/or an inpatient stay in a ward for monitoring. Very uncommonly, a further surgical procedure may be required to stop nosebleeds. If you have had a continuous nosebleed, even



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if it has stopped on its own or has been treated, please contact the RATIONALE-15 study team on the telephone number provided.

- **Medications:** The risk of bleeding is higher if you are taking medications that thin your blood such as warfarin, apixaban-like medicines or clopidogrel-like medicines. People taking these medications are excluded from the RATIONALE-15 study. If for any reason you have taken any new medication in the 7 days before the biopsy procedure, please let us know. Please do not stop any regular medicines without medical advice to do so.
- **Infection:** infections following nasal biopsy are very rare. If you get redness and/or tenderness/pain in the few days following the biopsy, you may need antibiotics.
- **Considerations:** Avoid blowing your nose for 2 weeks after the biopsy. Do not pick your nose or put your fingers over the area. Avoid strenuous exercise or straining on the day of the biopsy if possible.
- **Follow up:** We will call you the day after the biopsy for a safety check and you will have 24/7 telephone access to a member of the study team for up to 3 weeks after the biopsy.

Other potential risks from taking part in this research study

- **Blood sampling** may cause slight pain and sometimes bruising. Occasionally, people feel light-headed, nauseous, or faint. The amount of blood taken at each visit is small and should be well tolerated by healthy adults.

What if we find something unexpected?

As we carry out several medical tests throughout the study, it is possible that we pick up previously unknown health issues (e.g. high blood pressure, abnormal blood results). If abnormal results or previously 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.

During the screening process, we will test your blood for HIV, hepatitis B and hepatitis C. 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



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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.

Are there any benefits from taking part?

There is no direct benefit to you of taking part in this study. By agreeing to have a nasal biopsy, you will be helping research which evaluates the immune response to vaccination in the nose, the site of infection of pneumococcus. Participants will benefit from receiving PCV15 vaccine which protects against 15 pneumococcus serotypes. No specific additional medical care will be provided through participation, and medical procedures are performed with the aim of determining eligibility and safety during the trial.

What other considerations do I need to know?

- **Contraception:** We require participants who could become pregnant to use contraception for at least one month before they receive their first vaccination, and for the entire duration of the study. Unless you are post-menopausal or have had a permanent sterilisation procedure, you will be required to use one of the contraception methods listed below and to have a pregnancy test at screening and before biopsy procedures and vaccination.

Acceptable effective contraception methods include:

- Oral, injected or implanted hormonal contraceptives (“the pill”, “the depot”)
 - Intrauterine device (IUD) or intrauterine system (IUS) (“the coil”)
 - Condoms or occlusive cap with spermicide
 - Sole sexual partner has had a vasectomy
 - Complete abstinence from sexual intercourse which could result in pregnancy (please note this must be in line with participants’ normal lifestyles, and declarations of abstinence during the study will not be sufficient)
- **Pregnancy:** If you were to become pregnant during the study, you should tell us immediately so that we can review study procedures and determine the appropriate safety follow up. With your consent we would follow you up to birth or end of pregnancy. Study procedures such as vaccination and inoculation will be suspended if pregnancy detected before them. If



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pregnancy detected after inoculation, we will need to assess the need for antibiotic treatment and discuss it with you.

- **Other vaccinations:** If during the study you require any vaccinations for health, travel, or occupational reasons, you should inform the study team before you have the vaccine. We ask you not to have any vaccines within 28 days (before or after) of the study vaccine. Exceptions to this are flu vaccines and COVID-19 vaccines which can be given within 14 days (before or after) of the study vaccine.
- **Identification:** We will ask you to bring a form of photographic Government issued ID to your first visit and provide your National Insurance number. A copy will be kept securely and checked at each visit by authorised members of the study team.
- **Medications:** If you begin taking any new medications during the study (prescribed or over the counter), please inform the study team.
- **Blood donation:** It would be best to avoid blood donation as we will be taking blood on a regular basis during the study.
- **Taking part in other clinical studies:** You should not take part in other clinical studies where drugs or vaccines are administered or where repeated blood samples are taken.

Do I have to take part?

No, it is completely up to you. 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.

You may also change your mind about participating at any time and withdraw from the study. This would not result in any penalty or change to your medical care. 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, unless you specifically request that the samples be destroyed before being analysed.

In exceptional circumstances (for example, if you were to become very unwell during the study), your participation in the study may be stopped early by the study team or the sponsor of the trial. If this occurs, we may ask you to still attend safety follow-up visits with your consent.



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Will I be reimbursed from taking part?

Study participants would be reimbursed for their time, travel, and the inconvenience of taking part in the study. The maximum reimbursement for any volunteer who completes all visits of the **nasal biopsy group** is up to £715. All participants will be reimbursed based on the following figures:

Study Visit	Visit type	Reimbursement
N/A	Screening	£110
Nasal biopsy 1	Biopsy procedure 1 (pre vaccine)	£150
Phone call 1	24 hours after biopsy procedure 1	£5
Day 0	Vaccination	£110
Day 7	Vaccination Follow-up	£90
Day 23	Vaccination Follow-up	£90
Nasal biopsy 2	Biopsy procedure 2 (post vaccine)	£150
Phone call 2	24 hours after biopsy procedure 2	£5
Phone call 3	3 weeks after biopsy procedure 2	£5

You may also receive reimbursement for any unscheduled visits you are asked to attend by a member of the study team. You would be reimbursed £90 per unscheduled visit. We will also offer a £10 payment (a shopping voucher of equivalent value) to study participants (once enrolled) that refer a friend that takes part in the study.

The sum reimbursed is on a pro-rata basis, so, if for example, you withdraw halfway through the study, or do not complete all study procedures, we would calculate your reimbursement based on the visits you have attended and samples that have been obtained. The reimbursement provided is considered to be reasonable amounts to cover the costs of participating in this research. There should not be any consequences for tax or benefits purposes. The reimbursement will be provided at different intervals of study involvement.



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Payments are made directly by bank transfer from the research site Oxford Vaccine Group to you. For this reason, we require participants to provide their bank details at the screening visit. 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.

What will happen to the samples I give?

- The study samples are analysed in University of Oxford and NHS laboratories.
- Samples taken will be used to look at your immune responses to the vaccine and to pneumococcus. Some bloods and nasal cells would be used to look at the pattern of genes being actively used by your body in response to the vaccine and during pneumococcal carriage. The response to infection and to vaccines is in part genetically controlled, so knowing the pattern of genes that are being used may help us to understand how individuals respond to vaccination and to pneumococcal carriage. As part of processing clinical safety samples, local NHS laboratories may be required to add the results to your medical records.
- We will send samples to other researchers working with us on this research project, including researchers within and outside the UK and the study funder (MSD, a commercial company) to conduct some sample analysis.
- Samples sent to research laboratories for processing will not have personal identifiers (they will be identified by study number and participant number only). However, your DNA is unique to you so it can never be completely anonymous.
- If you choose to take part in this study, you will be asked for permission to store samples (including cells and DNA) in the Oxford Vaccine Centre Biobank. This is a collection of samples, like a library, and allows the samples to be stored once this study is finished. You can choose to say no to the biobank but continue with this study. If you decide not to consent for the biobank, the remaining samples will be destroyed.

We will not be able to provide you with individual results for any of the immune response tests performed. Safety and Screening test results can be shared if



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What happens to my data?

An online screening questionnaire is used to determine your eligibility. For those participants who proceed to take part in the study, the data from the screening questionnaire will be kept with their study records. For those who do not proceed to participate in the study, all answers from the screening questionnaire will be kept until the end of the study recruitment period and then will be deleted. If you supplied your medical history or underwent screening but were not vaccinated in the study either because you were not eligible or decided not to take part, then any data collected will be kept until the end of the study.

Responsible members of the University of Oxford, regulatory authorities and study monitors may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

You will be given a study number, which will be used on study paperwork and samples. We will be using information from your medical records in order to undertake this study and will use the minimum personally identifiable information possible. We may need to view your ID (driver's licence, passport or national ID card), and will record either your national insurance or passport number for TOPS database registration and payment processing. This will be taken at the screening visit. We will securely retain this information until the end of the study. Your bank details will be stored for 7 years or in line with Oxford Vaccine Group financial policy.

General Data Protection Regulation (GDPR) requires that we 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, based in the United Kingdom, is the Sponsor for this study and the 'data controller' and will use your personal information to contact you about the research study and make sure that relevant information about the study is recorded for your care in relation to your health during the study, and to oversee the quality of the study. Your personal information will be kept confidential and handled in accordance with data protection laws in the UK. We will be using information from you and your medical records to undertake this study. We will use the minimum amount of personally identifiable information.



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Study staff will ensure that participants' data is pseudo-anonymised other than for uses (e.g., notification to UKHSA and communication with the GP) about which the participants will be consented for. Participants will be identified by initials and a participant ID number on the study paperwork. Your email address is required for the electronic diaries, in order for them to function. Only designated site staff and the data managers(s) will have access to view your email address and you will need to consent to this.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research study and as explained in this information sheet, for example text messaging service providers/companies to send study-related text messages to you. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

Study data may be stored electronically on a secure server by the University IT team, and paper notes will be kept in a secure location at each study site or as outlined in local SOP's. We will store the research data and any research documents with personal information, such as consent forms, securely for up to 25 years after the end of the study, or as per national regulatory requirements. Anonymised research data may be kept indefinitely. It will not be possible to identify you in any publication or report.

You can stop being part of this study at any time, without giving a reason, but we will keep the information about you that we have already obtained, including samples and symptom diary data. If you prefer, you can request for the samples to be destroyed (if they have not already been analysed).

If you have agreed that samples can be retained for future research, then your personally identifiable information will be kept with restricted access solely for the purposes of sample management. Samples will be provided for future research only in a form that does not identify you.



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At the completion of the study, unless you consent otherwise (e.g., if you request to be informed of other studies), your personal details will not be used to contact you other than in exceptional circumstances concerning your safety. If you consent to take part in another study carried out by Oxford Vaccine Group personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

If you agree to future contact (e.g., to be informed of other studies) we will continue to store your consent form within the study records and personal information (e.g., name, DOB and contact details) in a password protected database. This will be archived on a university server with restricted access and kept indefinitely, or until the study team feel that it would no longer be required, at which point it will be deleted. This will be held separately from the study data, and you can request at any time to have your details removed. If you have not consented to being approached for future studies, your contact details will be stored for 5 years after the end of the study to provide copies of study results and allow sufficient time for study data cleaning.

General Data Protection Regulation (GDPR) provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we use your information:

- At <https://www.hra.nhs.uk/planning-and-improving-research> and www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending us an email to info@ovg.ox.ac.uk
- By ringing us on 01865 611400

Additional Information

- The study is **sponsored** and organised by the University of Oxford.
- The study is **funded** by Merck Sharp & Dohme.



Oxford Vaccine Group
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- **Private insurance:** If you have private medical or travel insurance participation in a study will not usually affect your cover if conditions are unrelated to the study, but to be certain you must tell your provider before you take part.

- **Confidentiality:** Information collected during the study will be treated confidentially. We will inform your GP that you are enrolled in the study and provide information so that your medical records can be updated. You will be required to consent to allow us to access your medical records, via your GP or via electronic records, to check your health before enrolling in the study and during the study, if you have medical events.

Responsible members of the University of Oxford, the relevant NHS Trusts involved in the research and the regulatory agency responsible for clinical studies 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.

- **TOPS database:** Volunteers participating in this study must not be enrolled in another study that involves investigational medicines or vaccines at the same time. The Over-Volunteering Prevention System (TOPS) is a national database which helps prevent volunteers from taking part in too many clinical studies. To check this, we will need your passport number (for all non-UK citizens) or National Insurance number (UK citizens). We will update the database when you receive a vaccine. The data is retained in TOPS for 2 years if you do not receive a dose of vaccine.

- **New Information:** Sometimes during a study new information becomes available that is important to let you know about. This may mean signing a new consent form. We will review new information or safety concerns and you would be kept fully updated.

- **Harm:** The investigators recognise the important contribution that volunteers make to medical research and make every effort to ensure your safety and well-being. The University of Oxford, as the 'research sponsor', has arrangements in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. In the event of harm being suffered, 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 may advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. If you are referred to the NHS during the study, then NHS indemnity operates in respect of the clinical treatment which may be provided.



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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 study protocol.
- Any test or procedure you received as part of the study.

Any payment would be without legal commitment (please ask if you wish for 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 study protocol or where the protocol wasn't followed.

- **Complaints statement:** If you wish to report a concern about any aspect of the study, you can contact your local study team at 01865 611400 and info@ovg.ox.ac.uk. You may also contact the sponsor, the University of Oxford, RGEA (Research Governance and Ethics Assurance) office on 01864 616480, or email at rgea.complaints@admin.ox.ac.uk. Reporting a concern will not affect the medical care you receive now or in the future.
- **Results of this research:** The results will be published in a scientific medical journal and may be presented at scientific conferences or meetings. You will be provided with a summary of the results and access to the full publication. This can take up to 2 years after the study is completed. Your individual results would not be identifiable, and you would not be identified in any report or publication (de-identified). The research data will be shared with collaborators who are organising or funding the research. 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.
- **Review:** 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 C Research Ethics Committee. The Oxford Vaccine Centre Patient Public Involvement group have reviewed the main participant-facing documents associated with this study (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.



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Register for the study or discuss with the team

We hope this information sheet has given you enough information to decide whether to volunteer for this study. If you would like further information about participating in research, please visit the following website:

<http://www.nhs.uk/conditions/Clinicaltrials/Pages/Introduction.aspx>.

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

If you are interested in taking part in this study, then please complete the online screening questionnaire at:

<https://www.ovg.ox.ac.uk/studies/rationale15>

If you have further questions about the study, please contact us at:

Email: info@ovg.ox.ac.uk **Tel:** 01865 611400