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# OXFORD VACCINE GROUP

# Persistence of the immune response after immunisation with Ebola virus vaccines (PRISM Study)

## Cohort 3 - Study Information Booklet

You are invited to take part in a study to assess the persistence of the immune response to Ebola virus vaccines. The study is being run by the Oxford Vaccine Group which is part of the University of Oxford.

Before you decide whether to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish. If anything is unclear or you would like further information please contact the study team (details below).

Thank you for taking the time to consider taking part in the study.

**Contact Details**

Oxford Vaccine Group

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## Who are the Oxford Vaccine Group?

The Oxford Vaccine Group, which is part of the **University of Oxford**, is an independent research team of doctors, nurses, play assistants and scientists. We carry out research studies of new and improved vaccines for babies, young children, teenagers and adults and teach doctors and nurses about immunisations. In the past 5 years alone, over 7000 participants in the Thames Valley area have taken part in our research studies.

## Why have I been invited to take part?

You have been approached as you received the two investigational vaccines against Ebola virus disease (Ad26-ZEBOV and MVA-BN-Filo) in the Phase 2 (EVOLVE) study conducted by the Oxford Vaccine Group. Up to 148 people from the Phase 2 study are being invited to participate in this study.

## What is this follow-on study about?

Our Phase 1 study with the Ebola virus vaccines Ad26-ZEBOV and MVA-BN-Filo (EVE) has demonstrated that administration of these vaccines as a 'prime' and 'boost' combination generates an immune response that is potentially capable of providing protection against the Ebola virus infection. This was followed by a Phase 2 study (EVOLVE) using the same vaccines. At present, we do not know whether this immune response is sustained for a long duration or is only short lived.

It is important to know the duration of the immune response to the vaccines, as it will help us to decide whether a further booster dose might be needed after the initial vaccinations and if so, at what interval will such a booster be required. The duration of immunity will also help us to determine the clinical circumstances in which these two Ebola virus vaccines are best used. In this study we will be taking blood tests to look at the duration of immunity; no further vaccines will be administered.

We would also ask your permission to contact you in the future, to invite you to take part in further studies evaluating the persistence of the immune response. For this purpose your contact details will be stored separately from your research data. You can request that your details are removed at any time.

## Who can take part in the study?

Anybody who has received the two Ebola virus vaccines in the Phase 2 (EVOLVE) study can take part in this study. We may exclude people with health conditions or medications that might suppress their immune system. We will also exclude anybody who has received any adenovirus or MVA virus based vaccine since their participation in the Phase 2 study.

## What happens in this study?

If you express an interest in taking part, a member of the Oxford Vaccine Group would contact you to discuss the study. If you are still interested after this and seem suitable for the study then we would organise for you to come to the CCVTM to attend the initial study visit where your eligibility will be checked. Study visits are timed so that they take place between 2 and 5 years after you received the Ebola vaccines.

This study (PRISM) would involve two clinic visits.

The first visit would take place 24-54 months after the primary Ebola vaccines and the second visit at least 6 months after the first.

At each visit you would have a blood test to study the persistence of vaccine-induced immune response (i.e. antibodies and white blood cells) and any relevant medical information would be collected.

Your first study visit would take about 30 – 45 minutes. We would sit with you and go through the study in detail and provide you with the opportunity to ask any questions you might have about the study and what is involved. You would be allowed as much time as you feel necessary before making any decision on whether to take part.

If you are willing to proceed, we would ask you to sign an **informed consent form.**

Following this signature we would:

- Review whether you meet the study inclusion/exclusion criteria
- Review any significant changes in your general health
- Review your medications if there was a significant change in your general health
- Review any vaccinations you have received since the initial study
- Take a blood sample of approximately 50ml

At your second study visit we would answer any questions that you may have and check that you are happy to continue with the study. We would also review any changes to your health, any medications or vaccinations you have received, and take a blood test of approximately 50ml.

## What would happen to any samples I give?

The blood samples collected during this study would be anonymised. The samples will be analysed at the Jenner Institute laboratory which is also part of the University of Oxford. We will conduct tests to assess your immune response to the Ebola virus vaccines. If you agree (as below), we will store some samples at our Biobank for future research on immunity and vaccination.

## What else do I need to know?

If you choose to take part in this study, we will be asking for your separate permission to store blood (including DNA and cells), in a collection of samples called a Biobank. Details of this will be provided to you in a separate booklet, after you are enrolled into this study.

You are free to say no to this and continue to take part in this study if you wish. If you do not wish for your samples to be stored in a Biobank they will be destroyed 12 months after the last participant has completed the study.

During the study period, the study team might contact you via email or text to remind you about your appointments or rescheduling of a missed appointment. After you have completed your participation in the study, we will contact you to inform you about the findings from the study.

## Reimbursement

All participants will be reimbursed for their time, travel and the inconvenience based on the following figures:

- Travel expenses: £15 per visit
- Inconvenience of blood tests: £10 per blood donation
- Time required for visit: £20 per visit

This is £45 per visit, so the maximum amount reimbursed will be £90. Reimbursement will be made in cash following the completion of the study procedures at each visit.

## What is expected of me during the study?

We would expect you to:

- Be willing to participate in the study and sign a written consent form
- Give correct and accurate information about your medical history and any current medical conditions
- Tell the study staff about any new medication or vaccine since your participation in the Ebola vaccine trial

## What are the advantages of taking part in the study?

There are no clear benefits to you if you take part in this study. By taking part you may help to establish the clinical use of the Ebola vaccines and provide important data to influence Ebola virus vaccine policy in future.

## Is there any side effect from taking part in the study?

You may experience some discomfort from the blood test, which can include bruising, fainting and infection at the needle puncture site. Risk for these should be no more than for a routine blood test.

## Would my taking part in this study be kept confidential?

**Yes**. All information that is collected about you during the course of the research would be coded with a study number and kept strictly confidential. Any information about you that leaves the clinic would have your name and address removed so that you could not be recognised (with the exception of letters sent to your GP). Your information would be stored on a secure server, and paper notes would be held by the Oxford Vaccine Group in a locked cabinet. Once the study has been completed, all documents would be archived in a secure facility for a minimum of 5 years. Files will be confidentially destroyed subsequently.

Your data is retained in case we need to contact you regarding any study related matters or if you wish to contact us regarding your participation in the study. With your consent, we may also contact you to inform you of future related studies.

In order to ensure that the study is being conducted correctly, the Clinical Trials and Research Governance Office (CTRG), University of Oxford, who are responsible for ensuring the appropriate conduct of the research on behalf of the research Sponsor (the University of Oxford) may inspect the study records without violating your confidentiality.

**What will happen to my data?**

We will be using information from you, and, if necessary and with your consent, your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will keep identifiable information about you such as contact details for 5 years after the study has finished in secure storage at the University of Oxford. We may need to store this information for longer if the vaccine is licensed: this will be kept under review. If this were the case, we would store research data at licensed, secure premises contracted by the University of Oxford for 15 years after the end of the study, subject to adjustments in clinical trials regulations.

In addition to the anonymised scientific data, we will also store documents containing personal information that you provide when registering for the trial (including contact details), medical information and signed consent forms during this archiving period. This data is retained for safety purposes – to enable the Study Team to contact you in the event that there was a safety issue which emerged after the study period.

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

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:

http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

Results of the study may also be published in scientific journals and presented at conferences. It will not be possible to identify you in any reports, publications or presentations.

You can find out more about how we use your information by contacting the Oxford Vaccine Group on 01865 611400 or email info@ovg.ox.ac.uk.

## Who monitors the conduct of the trial?

The trial will be under continuous monitoring by the research team at the Oxford Vaccine Group. The Clinical Trials Research Governance (CTRG) team on behalf of the Sponsor (The University of Oxford) will provide further oversight.

## Is there anything else I should know?

If you have private medical insurance, you are advised to contact your insurance company before participating in this study. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

## Where can I get advice on whether to take part?

We are happy to answer any questions you might have and contacting us does not commit you to taking part in the study. For independent advice you can contact **INVOLVE** (www.invo.org.uk) which is a government funded national advisory group supporting those considering involvement in NHS, public health and social care research. Please feel free to discuss this study before deciding whether or not to participate.

## What if I wish to complain?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Oxford Vaccine Group on 01865 611400 or email info@ovg.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

At any time during the study, and for any reason, you would be entirely free to change your mind about taking part, and to withdraw from the study. We would keep the information and samples already collected, however, all data and samples would be anonymised. This would not affect your subsequent medical care in any way.

## Who is organising and funding the study?

The study is being funded by Innovate UK and internally by the Oxford Vaccine Group. No member of the study site staff including the Chief Investigator is receiving direct financial benefit from conducting this study. The study is being sponsored by the University of Oxford.

## Who has reviewed and approved this study?

The study has been reviewed by the study sponsor (the University of Oxford). It has been approved by South Central-Oxford A Research Ethics Committee (17/SC/0169).

## So, in summary, what would happen if I decide to take part in the study?

- We would arrange a suitable time and date for you to attend two study visits at the CCVTM with six months in between.
- If you are willing and eligible, you would be enrolled into the study at your study visit, after providing informed consent.
- We will go through your medical/medication/vaccination history and obtain one blood sample at each visit.
- We would ask your permission to contact you again regarding future vaccine related research; you could say no to this and still take part in this current study.
- You would be reimbursed up to £90 for your time, travel and inconvenience.

## What do I do now?

**Thank you** for considering taking part in this study. You do not need to make a final decision straight away. If you wish to discuss any element of the study further, then please contact us by either:

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

Yours sincerely,

Dr. Matthew Snape
Chief Investigator
Consultant Vaccinologist and Paediatrician
Honorary Senior Clinical Lecturer

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## Informed Consent Form

Participant Name: _____ Participant Number: |___|___|___|___|

*Please **initial** in each box if you agree with the statement*

I have read the 'Persistence of the immune response after immunisation with Ebola virus vaccines' Cohort 3 Study Information Booklet version __. __, dated __ __/ __ __ __/ __ __ __ __. ☐

I have had the opportunity to discuss the study, to ask questions about the study and I am satisfied with the answers and explanations that have been provided. ☐

I have spoken with Dr/Nurse_____. ☐

I understand that I am free to withdraw from the study at any time, without having to give a reason for leaving and without any effect on my medical care. ☐

I agree to OVG storing my personal information as described in the information booklet. ☐

I agree to OVG taking and storing my blood as described in the information booklet. ☐

I consider these samples a gift to the University of Oxford and I understand I will not gain any direct personal benefit from this. ☐

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the study team, the University of Oxford (Sponsor) or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

**If all of the applicable sentences above are initialled, meaning "yes", then please continue:**

I voluntarily agree to take part in this study. ☐

**Optional:** I give permission for the study team to contact me to invite me to participate in future research by the Oxford Vaccine Group. ☐

Name (PRINT NAME): .....

Signature: ..... Date: |___ ___| |___ ___ ___| |___ ___ ___ ___|

Investigator/Nurse Name (PRINT NAME): .....

Signature: ..... Date: |___ ___| |___ ___ ___| |___ ___ ___ ___|

*Top copy retained at OVG site and bottom copy given to participant*


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