OXFORD VACCINE GROUP

Investigating a new Vaccine Against Meningitis B in OXford

VAMBOX

Study Information Booklet

You are invited to take part in a study to test a new vaccine against Meningitis B, which is an important cause of meningitis and septicaemia in children and adolescents. 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.

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

Contact Details

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Glossary

Neisseria meningitidis – A type of bacteria that is an important cause of meningitis and septicaemia in the UK. Exists as several subtypes.

Meningitis B – Meningitis caused by the *Neisseria meningitidis* type B.

ChAdOx1 MenB.1 – The new vaccine candidate we are testing in this trial; the **Study Vaccine.**

Bexsero® **–** The current available vaccine against Meningitis B which is given to babies routinely in the UK. Used as the **Control Vaccine** in this trial.

Trumenba®- Another licensed vaccine against Meningitis B.

Serum Standard – A reference blood sample that contains antibodies against vaccines, for use in laboratory testing to enable standardisation of results across laboratories worldwide.

Who is the Oxford Vaccine Group?

The Oxford Vaccine Group, which is part of the **University of Oxford**, is an independent research team of doctors, nurses and play assistants. 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 7,000 participants in the Thames Valley area have taken part in our research studies.

Why have I been invited to take part?

We are inviting healthy adults aged 18 to 50 years old to take part in this study. We use various ways to contact potential volunteers, including the Electoral Roll and the National Health Applications and Infrastructure Services (NHAIS) who holds the central NHS patient database (Open Exeter). This database identifies all persons within the local area who are in the appropriate age range.

What is Meningitis B?

Neisseria meningitidis is a type of bacteria that can cause meningitis (infection of the lining of the brain) and septicaemia (blood poisoning), particularly in infants, children and adolescents. There are several different types of these bacteria which are often labelled with a letter. *Neisseria meningitidis B* is one of these types and the disease it causes is called Meningitis B.

In 2015/2016 in the UK there were 805 documented cases of invasive meningococcal disease (that is, disease caused by *Neisseria meningitidis;* either meningitis or septicaemia), with 43 deaths. *Neisseria meningitidis B*, or Meningitis B, accounted for 55% of the total number of cases, with most of the disease in infants and younger children.

What is the purpose of this study?

In this study we are testing a new vaccine against *Neisseria meningitidis B.* There are two current vaccines against Meningitis B called Bexsero® and Trumenba®. However, these vaccines commonly cause side effects (fever and pain); require two to three injections to establish immunity; and are reasonably expensive (RRP £75 per dose). The Oxford Vaccine Group is therefore proposing a new vaccine, which may produce a better immune response, be cheaper and require fewer doses. This study is being conducted to evaluate the safety of the vaccine and how well it stimulates the immune system against meningitis B in comparison to the current vaccines. We are aiming to recruit 79 to 90 participants to take part in this study (exact number may vary).

What vaccines are given in the study?

If you join the study, you would be allocated to receive the study vaccine, or the control vaccine Bexsero®, or both. One group will only receive Trumenba® vaccine.

The study meningitis B vaccine (ChAdOx1 MenB.1) is made up of a carrier virus and one meningitis B protein. The carrier virus is a chimpanzee adenovirus (known as ChAdOx1), which is not known to cause disease in humans, and cannot replicate (multiply) itself in your body. It has been genetically modified so that it produces a protein which looks like a meningitis B protein. This protein is normally found on the surface of meningitis B bacterium. Antibody produced by your immune system against it can then prevent meningitis B infection. The vaccine does not contain the meningitis B bacterium and cannot cause meningitis B disease.

This study vaccine has never been given to humans before. Animal studies showed that the vaccine was safe to give and capable of stimulating the immune system against meningitis B. Additionally, similar virus-based vaccines have been developed for vaccines against Malaria, 'Flu and Tuberculosis. All have been safe and very well tolerated in human clinical trials to date. Two different doses (low or high) of the study Meningitis B vaccine are being used.

If enrolled, you will be allocated to one of eight groups as described below. Allocation will happen in order of recruitment with preferential recruitment initially to groups 1, 2 and 3. You will be told which group you are allocated to. See Figure 1 on the next page for an overview of how the trial is organised.

Group 1 - Low dose arm – This group will consist of 3-6 individuals who will receive a single dose of ChAdOx1 MenB.1.

Group 2 - High dose arm –. This group will consist of 10 participants assigned to receive a single dose of the higher dose of ChAdOx1 MenB.1.

Group 3 - High dose plus booster arm – this group will consist of 8 participants who will receive the high dose of ChAdOx1 MenB.1, with a repeat booster dose at 6 months.

Group 4 - Bexsero® with high dose ChAdOx1 MenB.1 booster arm – this group will consist of 8 participants who will receive a dose of Bexsero® at Day 0 with a booster high dose of ChAdOx1 MenB.1 at 6 months.

Group 5 - Bexsero® Control arm – This group will consist of 10 individuals who will receive two doses of Bexsero® at Day 0 and Day 28 as per adult licensing. This group will act as a control to groups 1 and 2.

Group 6 - Bexsero® 6 month boost control arm – This group consists of 8 individuals who will receive Bexsero® doses at Day 0 and 6 months. This group will act as a control for groups 3 and 4. If participants choose to be a part of the serum standard, they would have a large blood donation at 7 months.

Group 7 (Bexsero® 6 month boost serum standard arm) – Single dose of Bexsero® vaccine followed by a second booster dose of Bexsero® vaccine at 6 months. Serum standard donation at 7 months.

Group 8 (Trumenba® 6 month boost serum standard arm) – Single dose of Trumenba® vaccine followed by a second booster dose of Trumenba® at 6 months. Serum standard donation at 7 months.

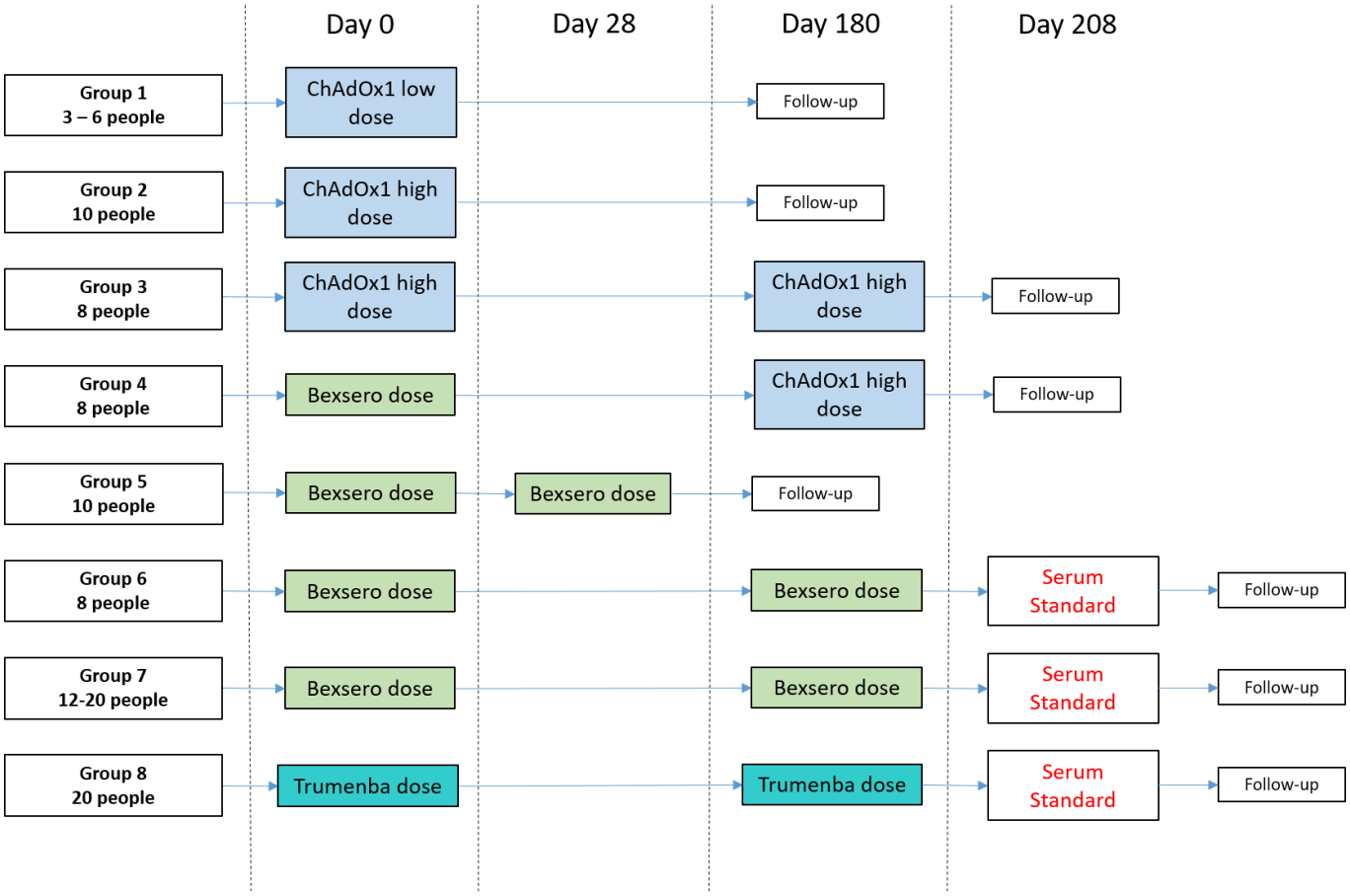


Figure 1: Overview of the trial. Follow-up can be found in tables 1-3.

If you are allocated to groups 5 or 6, you will receive two doses of a licensed vaccine against meningitis B, Bexsero®, either 1 month (group 5) or 6 months (group 6) apart. Group 4 will be given one dose of Bexsero® followed by the study vaccine at 6 months. Bexsero® is used as a control in this study to allow comparisons with the study vaccine. The final group will receive Trumenba® vaccine and the safety of this against the study vaccine will be examined. Groups 6, 7 and 8 will donate a blood sample known as a serum standard. Serum standards are important biological reference materials that enable standardisation of laboratory testing of antibodies against meningococcal B bacteria.

This study is being done primarily to make sure that the vaccine is safe to be given and understand how well it is tolerated by those who receive it. However, the study will also give some information on how it may help your body to protect against meningitis B infection. This will also help to find out whether it might be able to protect babies and children.

Since this is the first time this study meningitis B vaccine is being given to people, we will do the study in 3 steps to make sure you are safe when taking part. Throughout the trial, we have an independent monitoring committee to decide if there are any problems with the vaccine at any given dose.

In the trial, the new vaccine will first be tested at a low dose (group 1 in Figure. 1). Then, if there are no significant problems with the vaccine, it will be tested at a higher dose (group 2 in Figure. 1). If there are no significant problems with this higher dose, then the remaining groups receiving the vaccine (groups 3 & 4 in Figure. 1) will be recruited.

If there is a significant problem with the high dose, but not the low dose, we will continue groups 3 and 4 with the low dose instead. If there is a significant problem with the low dose, we will pause the study and ask the monitoring committee to decide how to proceed e.g. if we should stop the study.

As the aim of this study is to assess if the study vaccine is safe (if it causes any side effects) and how people feel after the vaccine ('tolerability'), participants should not assume they will gain protection against Meningitis B by their involvement in this study.

Who can take part in the study?

We are keen to recruit **healthy volunteers** who are:

- Willing and able to take part and able to attend all visits
- Aged between 18 and 50 years old, inclusive
- Willing to allow us to communicate with their GP to notify them of enrolment and to verify the medical history
- (**Females**) Willing to use effective contraception from 1 month prior to starting and for 3 months after the last vaccine

You would not be able to take part if you:

- Have significant medical problems
- Have previously had meningococcal disease
- Have received or plan on receiving a vaccine within 30 days of any vaccine in the study
- You have had a vaccine against Meningitis B
- You have had an adenovirus based vaccine (usually as part of a trial) - groups 1-4 only
- Have had a serious allergic reaction to vaccines
- Have or are planning on donating blood within 4 months of the start of the trial
- (Females only) Are pregnant or breastfeeding

What are the benefits of taking part?

Information from this study may help doctors learn more about this study meningitis B vaccine. This information may help us to make a vaccine that can protect babies, children and adults against meningitis B. The serum standards may enable standardisation of meningococcal B antibody testing across laboratories, to better evaluate meningitis B vaccines more broadly.

What side effects or risks can I expect from this study?

You may have side effects while on this study; these are outlined below. We will observe everyone in the study for any side effects, particularly in the first seven days after receiving a vaccine with an eDiary that you will fill in. Side effects may be mild or serious. Most effects will stop shortly after receiving the vaccine. In rare cases, side effects can be serious or prolonged, although no serious concerns have been raised in human trials for other similar virus-based vaccines. It is important to notify the study team if you are at all worried about your symptoms.

You may take medicines after you've received a vaccination to help lessen side effects; for example, if you have a fever you could take paracetamol to help treat it. Any medication you have taken during the study should be recorded in your ediary. If you have a severe reaction, we may give you medicines to assist you.

Vaccination

In general, the known risks following vaccination are minor and brief (lasting a few days). As with any vaccination, the following events could occur:

- Pain, redness or swelling of your arm around the spot where the vaccine was injected
- General: fatigue, headache, fever, gastrointestinal symptoms such as nausea (feeling sick), vomiting, diarrhoea or abdominal pain

As with all injected vaccines, unexpected, severe allergic reactions may very rarely occur. An allergic reaction can be recognised by itchy skin rash, swelling of the face, difficulties in breathing and swallowing or by a sudden drop in blood pressure. If such reactions occur, they usually start very soon after vaccination. That is why it is important that you stay at the study site for at least 60 minutes if you received the Study vaccine or 15 minutes after vaccination if you received Bexsero® or Trumenba®, where all medical equipment and personnel are available to treat an allergic reaction.

Study meningitis B vaccine

Adenovirus vaccines have previously been trialled in human volunteers, protecting against diseases other than meningitis B. These were not associated with serious side effects.
Animal studies conducted to date have shown this vaccine to be capable of stimulating the immune system against meningitis B. There were some minor changes in routine blood results one month after injection, but were not associated with any clinical problems
As it is the first time that the study vaccine will be tested in humans there might be side effects that we don't yet know about. If any new side effects are identified, from this study or from animal studies, we will tell you.

Bexsero® and Trumenba® Vaccines

Like all vaccines, the control meningitis B vaccine, Bexsero®, can cause side effects, although not everybody gets them. If there are side effects, they usually happen in the first 3 days after vaccination and they do not last for a long time.

The most common side effects of the control vaccine are (seen in more than 1 out of 10 vaccinated people):

- Local side effects at the injection site: pain, swelling, hardening and redness.
- General side effects: headache, nausea (feeling sick), generally feeling unwell, muscle pain, joint pain, and chills.

Blood sampling

This study involves several blood tests. Taking blood samples may sometimes result in bruising to the area and some people can feel faint. If you were feeling faint, our staff would ask you to stay at the clinic until you felt well again.

Those participants donating a serum standard will have extra blood tests taken at Visit 12 (between 200ml to 315ml). To do this we will insert a cannula (a thin, flexible tube) into your arm.

It is sensible to ensure you have drunk plenty of water/juice and had something to eat before blood tests to help your body adjust quickly and avoid feeling faint. You would be welcome to stay with us until you feel ready to go home.

Safety

At different times during the study, a group of experts will look at the side effects to decide if it is safe to proceed from the low to the high dose of the study vaccine; give a second dose; or to vaccinate more people. The group of experts can also meet at any moment, if needed, to discuss the safety of the study.

Throughout the study, the safety outcomes of the participants in all groups will be monitored. This will be done by monitoring of symptoms at visits and through the eDiary.
You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if you need emergency care during the study. The medical staff can then contact your study doctor or nurse if needed to ask about the vaccine or product you received.
You would have access to a study doctor 24 hours a day until the end of the study. It would be very important that you stay closely in touch with the study team and let us know as soon as you get a temperature or if you were unwell in any way.

We would ask you provide contact details of a person who can act as a 24 hour contact in the case of an emergency or needing to contact you urgently (those receiving the study vaccine, groups 1-4 only), and provide contact details of any doctors treating you. We may contact these people if we are not able to contact you in the two weeks following vaccination and will hold their details for the duration of the study (one year).

We will also check your haemoglobin if, at the Visit 12, you were donating the larger blood volume of 200-315ml. This is to ensure it is safe for you to give this larger volume of blood.

Pregnancy

You should not take part in this study if you are pregnant or breastfeeding. As this is the first time this vaccine will be given to humans, there is no information about how the vaccine could affect an unborn baby. Female participants must be willing to use effective contraception from one month prior to starting and for 3 months after the last vaccine to avoid pregnancy.
If you get pregnant during this study, inform the study staff promptly. You would not receive any more vaccine but may remain in the study for follow-up. You may be asked questions later about the pregnancy and the baby.

Study procedures

- **Recruitment**

If you express an interest in taking part, a member of the Oxford Vaccine Group will contact you by telephone to discuss the study and answers any questions you may have. Following this, if you are interested and seem suitable for the study then we would arrange for you to come to our clinic for a screening visit.

- **Screening Visit**

The purpose of screening is to assess whether you are able to participate in the study. The screening visit takes about 90 minutes. We would sit with you and go through the study in detail. This visit would provide an opportunity for you to ask any further 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 wish to proceed, we would ask you to sign an **informed consent form**. Only once this is signed would we then start any study procedures.

We would ask you questions about your health and take a blood sample to ensure you are healthy. All groups would have a physical examination, including an ECG ('heart tracing') and a urine sample. Blood will be screened for HIV, hepatitis B and C. For all females, we would perform a pregnancy test on your urine sample.

During your screening you would be asked to provide your National Insurance number (or passport number if you do not have a National Insurance number). This would be entered on to a national database which helps prevent volunteers from taking part in too many clinical trials. The Trial Over-volunteering Prevention Service (TOPS) database is to ensure safety of all our participants in this study and therefore if you are unwilling to have your information submitted on TOPS you would not be able to take part in our study. More information can be found at http://www.hra.nhs.uk/about-the-hra/our-committees/the-over-volunteering-prevention-system/.

We would also ask for your consent to contact your GP to obtain any relevant medical history that may affect your participation in the study. If needed, the study staff might ask for more blood or a urine test to be sure you are healthy before you can receive the vaccine.
Once the study team have confirmed your suitability for the study, we would inform you and arrange a date for your first visit. Your participation in this study is at the researchers' discretion.

Is coming to screening a commitment to taking part?

No. It is an opportunity to meet with the study staff and ask questions. You do not need to make a decision there and then.

Overview of study visits

You would be expected to do the following during the study:

- You would need to come to our study clinic at the Churchill Hospital for 11 (groups 1, 2 & 5) to 14 (groups 3, 4 & 6) scheduled visits. The schedule/dates for these visits are shown in Tables 1-4 on page 9. These visits last 30 minutes.
- You would receive 1 or 2 vaccinations as an injection in your upper arm.
- You would get the first vaccination during the first study visit after the screening period (at Visit 1).
    - If you are in group 5, you will receive an additional Control vaccine 1 month later
    - If you are in groups 3, 4 or 6, you will receive an additional Control or Study vaccine (as applicable) at six months.
- After each vaccination you would need to stay at the clinic for 60 minutes (Study vaccine) or 15 minutes (Bexsero® or Trumenba®) so that you can be observed. Your vital signs (blood pressure, heart rate and temperature) will be checked again to make sure you are well before you leave the clinic.
- During the study visits, the study staff would collect information to check the effect of the vaccine.
- We will review and check the eDiary entries you have made.
- You would be asked to tell the study staff about other hospital or GP visits, unscheduled healthcare tests (lab tests, X-rays etc.) or procedures (e.g. Endoscopies, surgery etc.)

Table 1: Summary of visits for Groups 1-2

Visit Number	Screening (V0)	V1	V2	V3	V4	V5	V6	V7	V8	V12	V13
Indicative Study Day		1	2	7	14	28	56	84 (12w)	180 (26w)	208 (30w)	365 (52w)
Medical history	x	x	x	x	x	x	x	x	x	x	x
Urine pregnancy test	x	x									
Blood sample	x	x	x	x	x	x	x	x	x	x	x
Vaccination		**x**									
e-Diary review		x	x	x	x	x					

Table 2: Summary of visits for Groups 3-4

Visit Number	Screening (V0)	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
Indicative Study Day		1	2	7	14	28	56	84 (12w)	180 (26w)	V8 + 1 day	V8 + 7 days	V8 + 14 days	208 (30w)	365 (52w)
Medical history	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Urine pregnancy test	x	x							x					
Blood sample	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaccination		**x**							**x**					
e-Diary review		x	x	x	x	x			x	x	x	x	x	

Table 3: Summary of visits for Group 5

Visit Number	Screening (V0)	V1	V2	V3	V4	V5	V6	V7	V8	V12	V13
Indicative Study Day		1	2	7	14	28	56	84 (12w)	180 (26w)	208 (30w)	365 (52w)
Medical history	x	x	x	x	x	x	x	x	x	x	x
Urine pregnancy test	x	x				x					
Blood sample	x	x	x	x	x	x	x	x	x	x	x
Vaccination		**x**				**x**					
e-Diary review		x	x	x	x	x					

Table 4: Summary of visits for Group 6

Visit Number	Screening (V0)	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
Indicative Study Day		1	2	7	14	28	56	84 (12w)	180 (26w)	V8 + 1 day	V8 + 7 days	V8 + 14 days	208 (30w)	365 (52w)
Medical history	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Urine pregnancy test	x	x							x					
Blood sample	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Serum standard													x	
Vaccination		**x**							**x**					
e-Diary review		x	x	x	x	x			x	x	x	x	x	

Samples

Blood would be taken at each visit. The amount would be between 6 mL (about 2 teaspoons) and 114 mL (half a cup) depending on the tests that will be done. Some of these blood tests will also be taken for genetic analysis to see whether a particular genetic makeup affects your response to the vaccine. For this reason it is necessary for us to record your ethnicity as this influences how we interpret your genetic tests.

The total amount of blood taken during the whole study (about 1 year) would be up to 1307 mL (about 6 cups), which is about 2 ½ "blood donations" to the UK Blood Transfusion Service. Your body would replace this blood after about three months.

There might be a case in which your blood needs to be retested or a urine sample taken to confirm test results. This might happen at your next visit or at an unscheduled visit that you would need to come to the clinic for. At this visit the study staff would take a sample of your blood (10 mL, 2 teaspoons) and collect a urine sample, as needed.

What will happen to the samples I give?

Your sample will be assigned a code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. The blood and urine samples collected during this study would be analysed in the Oxford University Hospitals and University of Oxford research laboratories. We would also send some samples to other researchers working with us on this research project, including researchers outside the European Union. These samples would be anonymised.

If you choose to take part in this study, we will be asking for your separate permission to store blood (including cells and DNA) samples, in a collection of samples called Biobank. Details of this will be provided in a separate booklet after you are enrolled into this study, and you are free to say no to the BioBank and continue to take part in this study if you wish. If your samples are going to the Biobank, a copy of your informed consent form (which contains your personal information), would be stored with those samples. If you do not wish for your samples to be stored in the Biobank, they will be destroyed 12 months after the last participant has completed the study.

What if any of my test results were abnormal?

If abnormal results or undiagnosed conditions are found in the course of the study these would be discussed with you and, if you agreed, your GP would be informed of these results. We would not report them to anyone else without your permission. For example, a new diagnosis of high blood pressure might be made. Any newly diagnosed conditions would be looked after by your GP.

Diary

After each vaccination, we would ask you to complete an online e-Diary, with a paper back up in case you were unable to access the internet. The first section will cover the first 7 days after vaccination and you will be asked to take your temperature, measure any injection site reactions (e.g. redness or swelling) with a ruler and record if you've had any symptoms or taken any medications. You will also be asked to fill in second section to record whether you've had any medications, symptoms or have been seen by your GP or any other health professional from day 7 and up to a month after each vaccination.

Reimbursement

Study participants would be reimbursed for their time, travel and inconvenience of taking part in the study. The maximum reimbursement for any volunteer who completes the whole study is £180 to £630 dependent on their study group. All participants will be reimbursed based on the following figures:

- Travel expenses: £15 per visit
- Inconvenience of blood tests: £10 per blood donation

- Time required for visits: £20 per visit

The sum reimbursed is on a pro rata basis, so, if for example, you choose to withdraw half way through the study we would calculate your reimbursement based on the visits you have attended and samples that have been obtained.
Payments are made directly by bank transfer in instalments during the study. For this reason we would require participants to provide their bank details at screening.
Bank details would be 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 General Data Protection Regulation (see below).
You may also receive reimbursement for any unscheduled visits you attend (if you have symptoms from the vaccine and need to be assessed). You would be reimbursed £45 per unscheduled visit, up to a maximum of £135 (equivalent of 3 unscheduled visits). If you do not require any unscheduled visits, you will not be reimbursed for this amount.

Do I have to take part?

No. We are looking for volunteers. Should you volunteer and later change your mind (for whatever reason) it is your right to do so, and you would not need to provide an explanation to the study team or anyone else. If you withdraw from the study, unless you state otherwise, any blood or tissue samples which have been collected whilst you have been in the study will be used for research as detailed in this Study Information Booklet. You are free to request that your blood or tissue samples are destroyed at any time during or after the study. Whatever you choose it's important that you are happy with your decision and it is not the role of the study team to decide for you. We would help present the details of the study and answer all your questions so you could make an informed decision.

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 recognized, with the exception of letters sent to your own GP. In order to enrol into this study, you would be required to sign a form, documenting that you consent for us to contact your GP. This is to inform him/her that you would be entering the study, and to ensure there are no medical reasons that would prevent you from taking part in this study. No one else would be told that you are involved in the study. We would only notify your GP of the results from any medical tests we performed with your permission.

Your information would be stored on a secure server, and paper notes would be held by the Oxford Vaccine Group in a locked cabinet. 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. We may also contact you to inform you of future related studies.

Responsible members of the University of Oxford and the 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. In addition, the following groups may inspect the study records without violating your confidentiality:

- Monitors who check that the study is being conducted to a high standard, including the Data and Safety Monitoring Committee (DSMC), an independent panel of experts responsible for trial safety.

- The Clinical Trials and Research Governance Office (CTRG), University of Oxford, who are responsible for ensuring the appropriate conduct of the study on behalf of the research Sponsor (the University of Oxford).

Anonymised data and samples would be sent to other researchers working with us on this research project, including researchers outside the European Union, and the study funders. Please note that your blood samples contain cells and DNA. Your DNA is unique to you so it can never be completely anonymous.

General Data Protection Regulation (GDPR)

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly.

We 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, and to oversee the quality of the study. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you to conduct the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The University of Oxford will keep identifiable information about you from this study for at least 5 years after the study has finished. We will securely store the anonymised research data and any research documents with personal information, such as consent forms, for at least 5 years after the end of the study. The need to store this information for longer in relation to licensing of the vaccine will be reviewed every 5 years.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to my data?

Once the study has been completed, all documents would be archived in a secure facility by Ardington Archives storage (Faringdon, Oxford). Files will be confidentially destroyed if storage is no longer required. For effective vaccines that may be licensed, secure storage of research data may be required for at least 15 years after the end of the study, subject to adjustments in clinical trials regulations. Your bank details will be stored for 7 years in line with University financial policy.

Professor Andrew J Pollard, or his successor, as Director of the Oxford Vaccine Group will have the responsibility for custody of the data. Further information about your rights with respect to your personal data is available at: http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

What will happen at the end of the research study?

The results of the research will be published in a scientific medical journal; this can potentially take a few years. All OVG publications will appear on the OVG website and you will receive a letter containing these results. Your

individual results would not be identifiable nor would you be identified in any report or publication. The results of the research will also potentially be used for future academic research within the Oxford Vaccine Group.
Once the last laboratory test is performed in the study, all samples will be destroyed, unless you have consented for them to be transferred to the Biobank. If your samples are going to the Biobank, a copy of your informed consent form (which contains your personal information), are stored with those samples.

What if there is a problem?

If you have private medical insurance, you are advised to contact your insurance company before participating in this trial. 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 Professor Andrew Pollard, Director of the Oxford Vaccine Group, (Tel: 01865 611400, Email: info@ovg.ox.ac.uk) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 (6)16480 or the Head of CTRG, email ctrg@admin.ox.ac.uk.
At any time during the study you would be entirely free to change your mind about taking part, and to withdraw from the study. This would not affect your subsequent medical care in any way.

Who is funding the study?

Up to July 2018, the study will be funded by the Medical Research Council under a Developmental Pathway Funding Scheme award. After July 2018 the study will be funded by a National Institute for Health Research (Biomedical Research Centre grant). The serum standard study arm is funded by the National Institute for Biological Standards and Control (NIBSC).

Who has reviewed and approved this study?

This study has been reviewed and approved for conduct by the South Central – Oxford A Research Ethics Committee (17/SC/0470), one of the national research ethics committees. This committee reviews research studies to protect the rights and wellbeing of the people taking part. In addition, the study has also been independently reviewed and approved by the Oxford University Hospitals NHS Foundation Trust Research and Development Department and the Medicines and Healthcare products Regulatory Agency.

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

- We would ring you to check that it is appropriate to include you in the research.
- You would then attend a screening visit at the CCVTM where you would have a blood test and urine test (and a pregnancy test for women). These are to assess your eligibility for the study.
- Following satisfactory screening results you would be enrolled into the study.
- You would be vaccinated with the study vaccine, Bexsero® or Trumenba®.
- You would be seen twice in the week after vaccination and fill in an eDiary
- You may have a second vaccination at one or six months and be followed up in the 4 weeks following this.
- We would continue to see you for the occasional clinic visit up to 13 months after the start of the study.

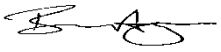
What do I do now?

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**
- website http://trials.ovg.ox.ac.uk/trials/vambox
- email **info@ovg.ox.ac.uk**

Yours sincerely,

Prof Andrew J Pollard
Professor of Paediatric Infection & Immunity
Honorary Consultant Paediatrician



Prof Brian Angus
Clinical Tutor in Medicine
Honorary Consultant Physician

Dr Blanché Oguti
Lead Research Fellow

Jamie Burbage
Lead Research Nurse

Investigating a new Vaccine Against Meningitis B in OXford

VAMBOX

Informed Consent Form

Participant's name: _____

Participant initials: _____

Screening number: VAM – 01 |___| |___| |___||___|

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

I have read the 'Investigating a new Vaccine Against Meningitis B in OXford (VAMBOX)' 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 affecting my medical care. _____

I have received detailed information about the treatment schedule and its importance. _____

I will bring the 24 hour contact reply slip to the first study visit, signed by my 24-hour contact. I agree that the study team may contact this person if I cannot be contacted during the study. These details are kept for the duration of the study (1 year). _____

I agree to my GP being informed of my participation in this study. I agree to my GP and/or other treating doctors being approached for additional information regarding my medical and vaccination history. _____

I agree to my National Insurance (if UK citizen) or Passport number being used to register me on the Trial Over-volunteering Protection Service (TOPS). I understand that it will be stored electronically for the duration of the study. _____

I understand TOPS is a Health Research Authority database that aims to prevent healthy volunteers from taking part in too many studies. I understand that only staff at OVG and other research units can use the database and OVG may call other units, or OVG may be called, to check volunteer details. _____

I agree that if a conflict is found on TOPS, OVG can share relevant information with other research groups and source relevant information from other research groups. _____

I agree to provide my bank account details including my account name, sort code and account number for reimbursement purposes. I understand that my banking details will be stored electronically for 7 years. ☐

I understand that my personal information will be shared to the extent required to process or verify eligibility of payments as described in the information booklet. ☐

I agree to refrain from donating blood for the duration of the study. ☐

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

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

I agree to my anonymised data and biological samples being used and stored as described in the study information booklet. ☐

I understand that some of my blood will be used to investigate the genetic factors determining the response to Meningitis B infection. ☐

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), regulatory authorities or the Oxford University Hospitals NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

Women only: I understand the need to ensure that I or my partner use effective contraception one month prior to first vaccination and continue to do so until 3 months after final vaccination. ☐

If all of the applicable sentences above are initialed, 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: ……
Signature: …… Date: |___ ___| |___ ___| 20|___ ___|
Investigator's/Nurses name: ……
Signature: …… Date: |___ ___| |___ ___| 20|___ ___|


oxford vaccine group