Southampton Clinical Research Facility
University Hospital Southampton NHS Foundation Trust
C Level West Wing, Mailpoint 218
Southampton
SO16 6YD
Tel: 023 8120 4989
Email: UHS.SouthamptonCRF@nhs.net
Website: www.uhs.nhs.uk/nihr-crf

Be on the TEAM: Teenagers against Meningitis

Evaluating the effect of immunisation with group B meningococcal vaccines on meningococcal carriage

Study Information Booklet – 4CMenB (Group 1)

We are asking you to join our research project to understand whether immunising teenagers with vaccines against 'Meningitis B' could protect them and the rest of the community against these potentially deadly bacteria.

This is a national study involving 24 000 year 12 (or equivalent) students across the United Kingdom. Teenagers at your college are being asked to take part by local researchers at University Hospital Southampton NHS Foundation Trust.. Please note that the University Hospital Southampton NHS Foundation Trust has not been given your name or contact details. Taking part in this study is voluntary and if you do not want to participate you do not have to reply to this invitation or attend our information session at your college.

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 your parent(s) or guardian(s). 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 the study.

http://beontheteam.uk/

What is the Be on the TEAM; Teenagers against Meningitis study?

- This study will see if immunising teenagers with MenB vaccines could reduce the risk of meningitis across the whole community
- Teenagers who take part will receive 2 doses of a Meningitis B vaccine
- These are licensed vaccines you would not otherwise receive, and will reduce your risk of meningitis
- You would also have two throat swabs 1 year apart
- There would be three study visits, over 12 to 18 months
- Visits would be held at your college

What is this study about?

Teenagers and young children are at increased risk of diseases such as meningitis and blood poisoning due to bacteria called meningococcus. Although these diseases can be serious, the meningococcus bacteria are 'carried' in the back of the throat of 1 in 10 teenagers without causing any symptoms. Most meningococcal disease in teenagers is due to Meningitis B (also known as MenB). We want to see if immunising teenagers with vaccines against MenB can reduce the number of teenagers carrying these bacteria in their throat. This would be important because it could mean that teenage MenB immunisation would not only help protect teenagers against these potentially deadly diseases, but also that babies, children and older adults are less likely to be exposed to the bacteria. In short, immunising teenagers with a MenB vaccine might mean lower rates of meningitis across all ages.

To study this we would like to collect samples from teenager's throats and compare rates of MenB 'carriage' in teenagers before and after getting a MenB vaccine. In this study we are using two types of MenB vaccine, 4CMenB (also known as Bexsero) and MenB-fHBP (also known as Trumenba) All participants in this trial will receive two doses of one of these vaccines with a 1-6 month interval between each dose. These vaccines are approved for use in the UK, and can be purchased, but are not in the routine vaccination schedule for teenagers in this country.

What happens in this study?

The study will enrol teenagers aged 16-19 years in Year 12/S5 or equivalent. Students at your college will receive the 4CMenB vaccine, and have three visits as shown below:

Visit 1	Visit 2 (6 months later)	Visit 3 (12 months later)
Throat swab + 4CMenB	4CMenB	Throat Swab

At the first visit, we will come to your college to discuss the study with you and answer your questions. If you are happy to take part we would ask you to sign a consent form and ask you about your medical history and any allergies. We will then briefly touch the back of your throat with a swab (like a cotton bud). Then you would receive your first dose of the 4CMenB vaccine. You would then privately fill in a one-page questionnaire asking about aspects of your social lifestyle that affect meningococcal carriage. At the second study visit you would receive a second dose of 4CMenB. After both vaccine doses we will contact you by email with a short survey about your study visit.At the third visit we would take another throat swab. To help remind you of your visits we will ask for your contact information to send you reminder messages before your next visit. You have the option of giving consent to be contacted should you wish to consider involvement in future research studies. If you do not want to be contacted about future studies, it will not affect you taking part in this study.

How many teenagers are taking part in this study? What is the study design?

Altogether 24 000 teenagers will take part in this study, who will be enrolled into one of three groups, as shown below.

Group	Study start	6 months	12 months	13-18 months Group 3 only
1 **(Your group)** (8000 students)	Throat swab 1st dose 4CMenB	2nd dose 4CMenB	Throat swab *End of participation*	
2 (8000 students)	Throat swab 1st dose MenB-fHBP	2nd dose MenB-fHBP	Throat swab *End of participation*	
3 (8000 students)	Throat swab		Throat swab 1st dose 4CMenB	2nd dose 4CMenB *End of participation*

How do we decide which group you are in?

Many colleges around the country are taking part in this study, and all colleges in any particular area will be allocated to the same study group. This allows us to more accurately study whether the vaccines might reduce carriage of the MenB bacteria in the throat. You will not have any say over which vaccine yourgroup receives.

Do I have to take part?

No. It is up to you to decide whether or not you want to take part. Please ask any questions you may have before you decide.

What are the risks and benefits of taking part?

4CMenB is a licensed vaccine approved for use to prevent MenB disease. This means that it has passed extensive safety testing. This vaccine is routinely given to babies at 2, 4 and 12 months of age in the UK. This vaccine is also licensed in the USA, where it is often given to students going to college/university to protect against MenB meningitis and septicaemia. As with most vaccines, immunisation with 4CMenB can cause some discomfort at the injection site, and can be associated with short lived headaches, generalised aches and pains or gastrointestinal upset. Approximately 2% of teenagers get a fever after the vaccine. As with all vaccines there is the very small risk of a bad allergic reaction, and staff are trained to deal with this. The safety of the vaccine in pregnant women is not known, so we would ask you to tell the study staff if you are pregnant or become pregnant during the study. More information about this vaccine is available at: https://www.medicines.org.uk/emc/files/pil.5168.pdf

A benefit of taking part in this study is that you will receive a vaccine against meningitis that is currently not offered to teenagers in the routine UK immunisation schedule. The MenB vaccine offered in this study is in addition to the MenACWY vaccine routinely given in year 9 in the UK, and offers protection against the most common form of bacterial meningitis affecting teenagers.

Some people find a throat swab either tickly or a bit unpleasant but this only lasts a few seconds. We would not individually feed back the results of the throat swab unless there was anything that needed treatment. This research will improve our understanding of meningococcal disease and carriage, and one of the best parts of this study is that it will help us to understand how vaccines can protect other people in the future.

All participants completing the 12 month swab visit will be entered into a ‘Be on the TEAM’ prize draw.

Who is doing this study?

This study is being conducted locally by University Hospital Southampton NHS FT. Nationally the study is being led by the Oxford Vaccine Group, part of the University of Oxford, who are sponsoring the study. The study is being funded by the Department of Health (through the NIHR and Public Health England). The MenB-fHBP vaccine is being donated by the pharmaceutical company Pfizer.

What will happen to the samples obtained in the study?

We will initially freeze your sample and later identify any meningococci we find. This will be done in a research laboratory, and samples will also be sent to a National Reference Laboratory in Manchester, and to Oxford University for detailed analysis. You would not be told if we find meningococcus in your throat, as this is very common, but we may contact you if we find unexpected bacteria. We would store your throat swab and any bacteria from it for use in future research studies looking at the bacteria in teenager's throats. No one using your samples this way would get any information identifying you and no one will be allowed to sell your samples or use them to make money.

What will happen to my information collected for the study?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information collected from you in order to undertake this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly. All information is kept strictly in confidence, meaning we will only tell those who have a need or right to know. Only authorised study personnel will have access to the data, which will be stored on a secure server hosted by the University of Oxford. Any paper notes will be held in your local study centre in a locked filing cabinet. Your personal information (name, date of birth, and contact information) is kept separately to your swab and questionnaire results. We will store your email on a secure University of Oxford server in order to email you a brief survey about your first two study visits. Otherwise we will only contact you about the study, the prize draw, or for medical reasons. With your permission, we may check your vaccination or medical history from child health records or your GP. Responsible members of the University of Oxford or host organisations may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations and check the accuracy of the research study. The only people at the University of Oxford who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The team who analyse your questionnaires and throat swabs will not be able to identify you and will not be able to find out your name or contact details.

Following completion of the study, all study records (which includes some personal data such as name, date of birth and contact details) will be retained at your local site until the youngest participant reaches 21 years of age, in case we need to contact you for medical reasons. Within the consent form, University Hospital Southampton NHS FT will seek your permission to store your personal data beyond this to contact you for future related research. If you agree then a copy of your consent form will be stored with your contact details (name, email address, phone number and DoB) for as long as they are kept, or until you request to be taken off this register. Anonymised data collected during the course of the study will be stored indefinitely, and may be passed on to other organisations which may include commercial organisations. Files will be confidentially destroyed when no longer required. As your throat swab sample will be kept for use in future research, your consent form will be held until the sample is used up or destroyed.

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. To

safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

What will happen if I don't want to carry on?

If you agree to take part and later change your mind, you can withdraw at any time just by letting us know. You don't have to give a reason. If you withdraw from the study, we will keep the information about you and your samples that we have already obtained.

What happens at the end of the study?

At the end of the study, we will let the colleges who helped out in the research know about the overall findings. Results will be posted on the study website http://beontheteam.uk/ and will be published in scientific medical journals. You will not be identified in any report or publication. The results from this study will help the Department of Health decide whether to introduce routine MenB immunisation for teenagers.

Who has reviewed this research study?

Before any research goes ahead it is checked by a Research Ethics Committee. This project has received a favourable ethical opinion from the South Central Research Ethics comittee.

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 your local study team at University Hospital Southampton NHS FT . You may also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk . 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 trial.

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

Over the entire course of the study we will come to your college, give you two vaccines, take two throat swabs and ask you to complete a brief questionnaire.

You are eligible to take part if you are in Yr12 / S5 and you:

- ☑ Are aged 16yo to 19yo at the first visit
- ☑ Have not had a MenB vaccine before (Trumenba® or Bexsero®)
- ☑ Plan to stay at your current college for Yr 12 and Yr 13
- ☑ Are not known to be allergic to components of the MenB vaccine
- ☑ Are not pregnant
- ☑ Don't have a known bleeding problem or are not on anticoagulant ('blood thinning') medication

What should I do now if I'm interested in taking part?

We recommend that you discuss taking part in this study with your parent(s) or guardian(s). You can consent to take part yourself. Your college will tell you what day the study team will be visiting, and members of the research team will be happy to discuss the study with you and answer any questions you may have. If you or your parent(s)/guardian(s) wish to discuss the study directly with the study team they can be contacted on 02381203132 or UHS.SouthamptonCRF@nhs.net..

Thank you for taking the time to read this information sheet.

Yours sincerely,

Prof. Saul Faust	**Anna Hardy**
Local Principal Investigator	Local lead nurse