

Bristol Children's Vaccine Centre

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Study to evaluate prevalence of meningococcal carriage in teenagers (SPIT)

Dear Student,

We are inviting you to take part in a research study of the effects of the new meningococcus B (MenB) vaccine (Bexsero) on meningitis bugs commonly found in the throats and saliva of teenagers. Taking part is completely voluntary. You are being asked because your college/school is taking part in the study. If you are 16 or older and think you might be interested, please read on.

Why are we doing this research?

Meningococcus is a bug that commonly lives in people's throats without causing any trouble. Meningitis and blood poisoning are very bad but rare diseases, which are caused by meningococcus (and some other bugs too). Very few people get these diseases, but teenagers and babies and young children are the most likely to be affected.

Vaccines stop the people who get them from getting ill, but can also stop them from passing on bugs to other people. Other meningococcus vaccines, like MenC for example, do this but we don't know whether the new MenB vaccine can do it too. Since 2015, babies have been getting this new MenB vaccine because they are the most likely to get sick. But teenagers are more likely to have the bug in their throat and to pass it on to other people. If we find out that the vaccine stops the bug being passed around, then it might well be offered to teenagers too.

Up till now studies like this one just used throat swabs – like a cotton bud on a stick – and usually only take just one from each person. You can find out more by taking several swabs from each person on different days. But we have found that taking swabs once a month isn't often enough to keep track of how the bug comes and goes. So now we want to take samples once a week and, because we think you would soon get fed up with throat swabs every week, we plan to ask you for samples of saliva (spit) instead. If we can show that this is the best way to do it, then everyone can do studies that way in the future.

What will happen if I take part in the study?

The study will finish in March 2017 with most things happening between now and Christmas. Everything will be done at your college/school during term-time.

- Sign a consent form to say that you are happy to take part.
- Give us a sample of spit by spitting into a small plastic container every week of term, up to about 20 in total. Each time this should take less than 5 minutes.
- 2-4 weeks after you start the study, have a short health check.
- Then have two MenB vaccine injections in your arm a month apart.
- Have a throat swab at each vaccine visit and then a final third one at the end (about March).
- Fill in a short questionnaire at each vaccine visit, one about things (like antibiotics and smoking) that may affect meningococcus, and the other asking how you felt about taking part and how we could improve the study.

What are the possible benefits of taking part?

By taking part you will help us work out the best way of preventing meningitis with vaccines in the future. By having the MenB vaccine you will be less likely to get serious meningococcal infection.

What are the possible side effects?

- Giving saliva is easy and has no risks.
- Throat swabs are not risky but can be slightly unpleasant for a few seconds because the cotton bud touches the back of your mouth.
- The MenB vaccine needle injections in your arm may hurt when they are given and your arm may be a bit sore and tender there for the next day or two. Sometimes people also get high temperatures, headaches, feel sick or have aches and pains the next day after the vaccine.
- Although we don't think the vaccine is harmful to pregnant women or their babies, to be on safe side, we think it would be better not to have the vaccine if you think you are pregnant, and to avoid pregnancy by using effective contraception during the study from before the first until after the second vaccine dose. If you do become pregnant during the study, we ask you to tell us – this information would be kept strictly confidential.
- Anyone taking part can contact us any time with any questions or concerns.

What happens if I say no?

That's no problem. Taking part is voluntary. This is perfectly fine – no need to say why.

What if I say yes, but change my mind later?

You can stop being in the study any time – no need to say why. If you want to tell us why, then that's fine too and interesting for us. If we think it's best for you not to be in the study for any reason, we will stop your involvement and let you know and why.

If you stop being in the study, we won't give you any more vaccines or take any more samples. If you are happy for us to use any information and samples we have already got when you stop, both for the study and for other research, that's great and we will do it. But if you don't want us to we will get rid of them without using them any further.

What will happen to my samples at the end of the study?

If there is any saliva or throat swab material left over when we have finished doing the study and if you are OK with it, we would like to save them indefinitely so we and other researchers can use them to do more research using them later. This might be research looking at the bugs, your immunity and your genetic code (DNA). 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. If you don't want to allow any of this you can say so on the consent form but still take part in the study.

What else do I need to know?

- The study is funded/supported by a charity (Meningitis Research Foundation), and the government (National Institute for Health Research Health Protection Research Unit – Evaluation of Interventions (Bristol) and Clinical Research Network, Public Health England, Department of Health) and the NHS (University Hospitals Bristol NHS Foundation Trust). It is being run by the University of Bristol and has been approved by the South West - Frenchay Research Ethics Committee.
- The information collected about you will be kept for 20 years. Apart from the people doing the study and other people whose job is to check that research is being done properly, no one else will be allowed to see or get any information about you like your name, date of birth etc. We give you a number when you join the study and use that for all the work we do, not your name or date of birth.
- Your own doctor (general practitioner – GP) looks after your healthcare so we will tell him/her that you have had the MenB vaccine. If you are OK with it, we will also check your health records about any other meningitis vaccines you've had in the past.
- When the study is done we will come to the college and tell you about the overall results and will write to you by email to tell you as well. But we won't tell you if you had meningococcus in your saliva or throat swabs because this is common and goes away by itself.

What if something goes wrong or I want to complain?

- The vaccine used in the study is a licensed medicine, so we don't expect anyone to be harmed by taking part. There is no automatic insurance protection to compensate you if you are injured, but you can still make a legal claim (e.g. if you think someone has done something wrong), and the University has Public Liability insurance that covers its legal liability in relation to study participation.
- If you want to complain about anything you did not like or disagreed with in the study, you can contact us anytime (see phone number and email at the top). You can also contact the Research Governance Team, University of Bristol, Level 3, Senate House, Tyndall Avenue, Bristol, BS8 1TH (research-governance@bristol.ac.uk).

What do I need to do now?

- Please talk about this information with your parent(s)/guardian(s) and anyone else you would like to get advice from. If you have any questions, please get in touch with us (contact details are at the top of page 1).
- If you want to take part in this study, just come along when we visit your school; we or your school will let you know when that will be. If you don't want to be involved, you don't have to do anything.

Thank you for taking the time to read and consider this information.



Professor Adam Finn (Study Doctor)