

MenAfriCar

Cross-sectional survey (including blood collection)

Consent form A1.1 Consent form for Adults (for local modification and translation as necessary)

Subject Number
Label



Information

Meningococcal meningitis – what it is and how it is spread

Meningococcal meningitis is common in [INSERT COUNTRY] and responsible for many deaths, especially in children. This disease is caused by a germ (bacterium) called the meningococcus. The meningococcus is spread from person to person by coughing or sneezing. In most people who are infected with the meningococcus, the bacterium establishes itself in the throat but does not spread any further – only rarely does it invade the blood and cause meningitis. Infection of the throat with the meningococcus does not usually cause any symptoms and so people who are infected do not usually know that this is the case. However, they can pass on the infection to someone else, who may become sick, and so they are called ‘carriers’. Because carriers are much more common than patients it is important to study carriers as well as patients when studying outbreaks of this meningococcal meningitis. This can be done by sampling the back of the throat with a thin stick coated at the end with a soft material (a swab) and testing this in the laboratory.

Vaccination against meningococcal disease

Vaccines that can prevent meningococcal meningitis have been used in Africa for over 30 years but these are only partially effective and epidemics continue to occur. However, a new vaccine has been developed, called a **conjugate** vaccine, which should be able to prevent epidemics. It will do this in part by preventing people from carrying the bacterium in the throat and spreading it to other people, something that the old vaccines could not do. Therefore, when the new vaccine is being tested it will be important to determine whether it prevents carriage as well as meningitis. To do this a group of scientists from Africa, Europe and the USA have agreed to work together on a study of meningococcal carriage in five countries in Africa (Chad, Ethiopia, Ghana, Nigerian and Senegal) before the new vaccine is introduced.

The meningococcal carriage study

To learn more about how many people carry the meningococcus in their throat before the new vaccine is introduced and why some people carry meningococci in their throat whilst others do not we are carrying out a study in five African countries where meningococcal infection is common. We are studying people in five different age groups to find out who are the most likely to be carriers. We would like you to help us by joining this study.

If you agree to take part in the study in the study, a member of the study team will

- ask you or someone in your household some questions about you household such as sleeping and cooking arrangements
- ask you some questions about yourself which will help us to learn if you are at risk of becoming a carrier and record this information on a questionnaire,
- collect a sample from the back of your throat using a swab. This is a little uncomfortable but not dangerous in any way.
- collect 5ml (about one teaspoonful) of blood to test for antibodies to the bacterium that causes meningitis.

You are completely free to decide whether you wish to participate in this study. If you decline to do so you will not be discriminated against in any way. You may withdraw from the study at any time and if you do so you will not discriminated against in any way.

If you agree take part in the study, the results of the tests that will be done on the swab and on the blood sample will be known only to the study investigators in this country and their collaborators in Europe and the USA but not to anyone else. Germs of any kind obtained from the back of your throat or part of the blood sample may be sent to England or other countries for special tests that cannot be done in your country. All information collected is completely confidential. Data will be stored in a computer database. This will be protected by a password and kept confidential.

Do you have any questions that you would like to ask now about the study? If you have any questions later about the study, you can contact the investigators through **xxxxxx**

Do you agree to participate in the study?

Consent

I confirm that I have had the nature of the meningococcal carriage study explained to me, that I have had an opportunity to ask questions, that I know the name of the person to contact if I have any further queries and that I have freely given my consent to participate in the study which involves completion of a questionnaire and collection of one throat swab and a single blood sample.

Name of person _____

Signature or thumbprint.....Date:_____

I confirm that I have witnessed the accurate reading of the consent form to the person named above and that he/she has had the opportunity to ask questions. I confirm that the individual has given their consent freely.

Name of witness _____

Signature of witness: _____ Date:_____