



The Royal College of Surgeons of England



Genetics of Otitis Media Study

Information Sheet (Adult Sibling)

Version 1, 1st October 2008, Mahmood Bhutta

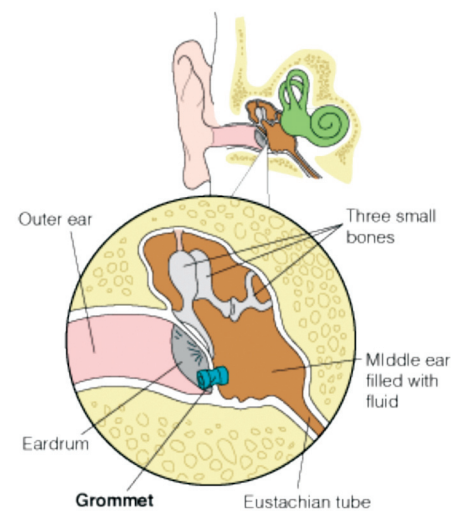
We are asking if you would like to participate in a research study. We are investigating the genes that may cause children to develop inflammation of their ear. This inflammation is called “otitis media” by doctors and may be seen as either repeated ear infections or as fluid in the ear called “glue ear”. Your sibling has otitis media, and this is why we are asking if you would like to participate.

This study will be the largest study of its kind anywhere in the world. We are looking to recruit 1,000 children and their families into this study. The research involves ENT surgeons in several hospitals working with the University of Oxford, the Medical Research Council's genetics unit in Harwell, the Wellcome Trust in London and the Royal College of Surgeons of England.

Before you decide if you would like to take part you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is this research about?

Inflammation of the ear (“otitis media”) is very common in children. Two-thirds of children will have had at least one ear infection by their fifth birthday, and almost all will have had at least one episode of fluid in the ear called “glue ear”. Usually children seem to grow out of these problems, but some children seem to get repeated ear infections or glue ear that just won't go away. If this happens, doctors often recommend a treatment called “grommets” which are little tubes surgeons put into the ear-drum to help dry up any fluid and stop infections or the “glue” coming back. This treatment has been recommended for your sibling, either because they have had lots of ear infections or because they can't hear well because the “glue ear” just won't go away.



Despite lots of research we still don't really understand why children get inflammation of their ears. There is a tube called the "Eustachian tube" that goes from the back of the nose to the ear and helps to keep the pressure in your ears at the right level (when you "pop" your ears, it is this tube that opens). Doctors think that this tube may be the cause of the problem, but they are not sure.

Recent research has shown that genes play a very important role in ear inflammation. Genes are bits of DNA, and DNA is the molecule that contains the blueprint for how our bodies develop and function. We know that ear problems seem to happen lots in some families and not at all in others. We don't know which genes are the cause of the problem, but we hope that this study may give us some idea. If we find out which genes make children more susceptible to ear inflammation, it will help us tremendously in understanding why these problems occur.

In this study we want to look at the DNA of your sibling and of your family from a sample of saliva (spit) to see if we can discover what might be the cause of ear inflammation. We will not be using the DNA for any other tests whatsoever, and will not give the information about your family or their DNA to anyone else. We need saliva samples from both parents and all siblings of the affected child.

What genes are you testing for?

At the moment we do not know which genes might cause ear inflammation. However, we have discovered some mice that seem to get the same problem as humans with their ears. We know from studying their DNA that there are problems with two genes called "Fbxo11" and "Evi1" that cause this problem. These genes seem to control how your ear reacts to levels of oxygen in the air. We want to find out if these genes cause the same problem in humans. We want to test the DNA of your family to see if there are problems with these genes.

What will happen to my DNA after the study is finished?

We would ask you whether you would consider giving your DNA sample as a 'gift' to us to allow for future research into the genes that cause ear inflammation. Collections of DNA already exist in the UK for other diseases, such as migraine, multiple sclerosis and heart disease, and the information from these DNA databases has been very helpful in UK scientists leading the world in understanding those problems. We want to create a collection of DNA for otitis media. This will be a public database of DNA, which means we will allow other researchers access to it for legitimate reasons. Other researchers will never have access to information on who the DNA came from.

You would not be contacted again in the future about using your DNA in this way, but approval for any new research would be obtained, and at all times your data would be kept anonymous. If in the future you lose capacity to consent, through mental or physical illness we would ask that we still be allowed to use your DNA and data, for the reason you have consented to.

Will you use my DNA for anything else?

No. If you agree to us keeping a small sample of your DNA we will make sure that it is only ever used for research into ear inflammation and never for anything else. We will never pass your personal details on to anyone else.

Is my personal information kept secure?

Personal information on you and your family is stored on a high security computer system at the University of Oxford. Access to this information is only allowed to the research team and to a selected few people at the University and in the hospital, whose job it is to check that the research is being undertaken correctly, including making sure your information is kept secure.

The DNA sample you give us is stored at a separate site, at the Medical Research Council's genetics unit in Harwell. Your DNA will be stored securely and anonymously, and is not linked to any of your personal information. Even if people somehow got access to your DNA sample at Harwell (which is extremely unlikely) they would have no way of knowing who it came from.

We take the security of your personal information very seriously.

Why have I been chosen?

Your family has been chosen because your sibling has developed repeated ear infections or has glue ear that won't go away. We are asking all families of children suffering from these ear diseases to take part.

What happens if I agree to take part?

If you agree to take part you we will need a sample of saliva (spit) from you to add to those from the rest of your family. The sample of saliva doesn't need to be very much, and you spit into a special container we will give you. Saliva contains DNA and we can get the DNA for this research from your saliva.

You can take the saliva containers home if you don't want to give us the sample at the hospital, and return these to the hospital or post them to the research coordinator at the address below. It is essential that the label that is put on the saliva container is kept with the correct sample. It is also essential that you return a signed consent form with your saliva sample.

As part of the study we will also ask your parent to fill in a questionnaire on the structure of your family. This will be kept confidential.

What if you find that my family is not what you expected?

We know that sometimes when we test DNA, families are not what they seem. For example, the man who is the father of a child may not turn out to be the biological father. If we find this information we will not pass this on to anyone else, including yourself or your family. Nobody will know this information other than the researchers.

Do I have to take part?

No. If you decide not to take part it will not affect your sibling's care in any way. If you do decide to take part you are still free to withdraw at a later stage, at any time, and without giving a reason. The DNA will then be destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, or if you think something has gone wrong, you should ask to speak to the ENT doctors looking after you, or to the research coordinator. The research coordinator can be contacted via the research nurse (07590 355672) or at the address below. Compensation for harm arising from an accidental injury and occurring as a consequence of your participation in the study will be covered by the University of Oxford. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against the University of Oxford (in respect of any harm arising out of the participation in the Clinical Study).

What will the results of the study be used for?

The results of this study will be used to hopefully better understand the genes that cause ear inflammation, which may help us to prevent this problem in other children in the future. The results will be published in a scientific journal, but without identifying any of the people who took part. The database of DNA we will create will also help other scientists in the future to investigate this problem.

Has this study been approved?

This study has received a favourable ethical opinion for conduct within the NHS by the Oxfordshire Research Ethics Committee. It has also been approved by your local hospital's research committee.

How can I find out more information?

Please ask any questions you have to the person who is taking consent from you to participate in this trial. If you still have more questions contact the research nurse (see below) who will be happy to help.

Research Nurse

Telephone: 07590 355672

www.har.mrc.ac.uk/geneticsomstudy

Address for saliva samples:

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