

PRISM: The Primary Care Streptococcal Management Study

PATIENT INFORMATION SHEET for CHILDREN aged 13-15yrs
MReC number: 06/Q1702/111 (Version 1; 07.07.2006.)

Before you decide if you want to join in it's important to understand why the research is being done and what it will involve for you. So please read this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to. Thank you for reading this.

Why are we doing this research?

We are trying to find out what causes sore throats. Some people who have sore throat will have an infection caused by a bacteria called streptococcus. We would like to be able to just give antibiotics just to those who have streptococcus, and are trying to find out which simple tests for streptococcus are the most accurate.

Why have I been chosen?

You have been chosen because your doctor/nurse thinks you have a throat infection.

Several hundred adults and young people will be taking part in this research

Do I have to help?

No! It is up to you. If you do,

- You will be asked to sign a form giving your consent or assent.
- will be given a copy of this information sheet and your signed form to keep
- you are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen if I agree to take part?

If you agree to take part you will need to answers some questions from the doctor or nurse about your sore throat

The nurse or doctor will take a throat swab sample from the back of your throat. This sample will be sent to a laboratory. In the laboratory a

technician will do tests on the throat swab to see whether you had the streptococcus bacteria in your throat, and also to see which tests for streptococcus are most accurate.

The throat swab is sometimes taken by doctors when they come with sore throats. In this study the nurse or doctors will need to take a throat swab in all people. Your doctor/ nurse will be able to get the results of the throat swab should they need it.

The nurse or doctor will then give you a diary to let us know how long your sore throat goes on for, how bad your sore throat is, and some questions about how. We also want you to tell us if you have any other symptoms with your sore throat such as headaches, or tummy pains.

The diary is simple, takes about 3 minutes to complete each day, and has room for up to 14 days entries if necessary. If questionnaires aren't returned we send brief reminders and if necessary a follow-up phone call.

You will be given a post-card to return if you see the GP again, or if you need hospital admission (this is very rare).

Someone from the research team will check your medical records after a few months to see whether you have had problems with sore throats or any similar infections, and any treatments you have needed.

Is there anything else to be worried about if I take part?

The throat swab can be slightly uncomfortable, and can make some people feel sick for a few seconds.

What will happen if I say that I do not want to take part?

If you do not want to take part the doctor will still treat your sore throat. You should tell your mum or dad (or the adult who is with you today) if you do not want to take part. If you want to find out more you can ask your mum or dad or the nurse or doctor who sees you.

What are the possible benefits of taking part?

We can't promise the study will help you but it might help treat young people with sore throats better in the future.

What happens when the research project stops?

If the tests for streptococcus work well then we hope they will become more widely available in the health service.

Who is organizing, paying for, and checking the research?

The study is paid for by the health service. Southampton University is doing the research. Before any research goes ahead it has to be checked by an Ethics Committee. They make sure that the research is OK to do. Your project has been checked by the Southampton & South West Hampshire Ethics Committee

Will anyone else know I am taking part?

If you agree to take part in the research, any of your records may be looked at to check that the study is being carried out correctly, but no one outside the GP surgery and research team will be given your name.

What will happen to the results?

The research will be published in medical journals. We will provide you with a summary of the results, but results will not be available for 3-5 years.

Contact details

If you have more questions you can ask: Jo Kelly or Jane Barnett at Aldermoor Health Centre, University of Southampton, Aldermoor Close, Southampton, SO16 5ST. Tel: 023 8024 1060

You can also ring local people who can tell you more about research:

Patient Advice and Liaison Service, Southampton City Primary Care Trust
02380 296929

Thank you for reading this.



University
of Southampton

School of Medicine
Primary Medical Care Group



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