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PRISM

The Primary Care Streptococcal Management Study

PATIENT INFORMATION SHEET MReC number: 06/Q1702/111 (Version 3. 29.09.06)

What is the purpose of this study? You are being asked to take part in a study. Before you decide whether you want to take part, please take time to read the following information carefully. The study aims to find which people with sore throat get better without problems, and whether we can target people with bacterial infections - particularly infections caused by the bacteria 'streptococcus' - who are more likely to benefit from antibiotics. As general practitioners, we want to move beyond saying, "it's probably just a virus" and to make a firmer diagnosis of the cause and likely outcome of the infection. We want to be able to make a better decision about which people need antibiotics to reduce the severity of their symptoms and to avoid serious complications. This will help avoid side effects when antibiotics are not needed, and to reduce 'resistance' resulting from overuse of antibiotics.

Why have I been chosen? Your doctor/nurse thinks you are suffering from a sore throat infection based on how sore your throat is and the inflammation (redness) in your throat.

Do I have to take part, and does this study affect my rights? Taking part in the study is voluntary. It is up to you to decide. If you decide to take part, you are free to withdraw from the study at any time without giving any reason and without affecting your current or future treatment in any way. Taking part in this study does not affect the care your doctor/nurse gives you (the study is simply observing the treatments the doctor/nurse provides, not asking doctors/nurses to do anything different), nor alter your rights to compensation or right to complain under normal NHS procedures.

What will happen to me if I take part, and what do I have to do?

If you agree to enter this study:

- You will need to answer a few questions from the doctor/nurse about your symptoms which will take 1-2 minutes (e.g. how sore your throat is, how difficult it is to swallow, how unwell you are feeling etc). This and other information (e.g. age, gender etc) will be used to try and predict those who need antibiotics.
- The Doctor/nurse will take a swab from each side of your throat which will be sent to the laboratory to test for streptococcal infection. A swab is sometimes taken by doctors and nurses when seeing patients – it is part of everyday practice. In this study the difference is that everyone is asked to have swabs taken. Some people find the throat swab slightly uncomfortable, and it can make some people feel sick for a few seconds.
- You will be given a post-card to return if you see the GP again, or if you need hospital admission (very rare).
- You will be asked to complete a diary of how your symptoms are at home, including measuring your temperature, answering a few questions, then returning it in the Freepost envelope provided. 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.

- The research assistant may ask you to consider talking confidentially about the concerns you have about sore throat in a one to one interview. This information will be recorded and transcribed for research purposes only, and remain strictly confidential

A research assistant is responsible for collecting the data in the study. He/she will probably not need to get in touch with you again about this - but may possibly, to clarify some questions if you are filling out the diary. You can also ask us any questions you like- for example if you find some of the questions difficult to answer.

Will any other information be collected? With your permission GP notes will be accessed to find out about previous infections and treatments, and any other treatment or care you might have needed for this infection. All these details will be kept fully confidential and used for research only.

What are the advantages and disadvantages of the study for me? The main disadvantage in taking part is the time involved in the diary. The main advantage is that you will help doctors and nurses better manage patients in the future.

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.

Will my taking part be kept confidential? All the information will be kept fully confidential. Even your GP will not see your answers to the questionnaire/diary. Your name will not appear on any papers or reports. To keep your information confidential all questionnaires will be identified by a number only, and stored on password protected computers in locked buildings which are alarmed when staff are not there. The computer based systems have secure encryption to ensure confidentiality for any data collected or sent over the internet. Regulations require that questionnaires are kept in secure locked cabinets for 15 years, after which they can be destroyed.

What if something goes wrong? If you have complaints about the way your illness was managed, this study will not affect your normal rights to pursue a complaint within the NHS in the normal way.

Who is organising, reviewing and funding the research? The study is funded and reviewed by the NHS Health Technology Programme and coordinated by three sites in the UK. Southampton University is coordinating the study locally. It has been approved by the Multi-Centre Research Ethics Committee (application no. 06/Q1702/111).

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

What next?

If you are happy to participate please sign the consent form to agree to participate which must be returned to the research team. Then, if you are happy to do so, you may leave the top two copies of the consent form with your GP in the freepost envelope and they will send the researchers their copy, (or alternatively post them in the freepost envelope which goes to the researchers). Take the bottom copy as your record of consent.

If you have any queries before you sign the consent form, or at any stage in the study please contact: Jo Kelly or Jane Barnett, Alder Moor Health Centre, University of Southampton, Alder Moor Close, Southampton SO16 5ST. Tel: 02380 241060.

(N.B. this number is only for queries regarding the study; if you have an urgent medical problem please contact your doctor in the normal way).

You can also contact the Patient Advice and Liaison service line which provides **general** information about research (see below)

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