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**The Sore throat Symptom and Complication study: DESCARTE**  
**(DEcision rule for severe Symptoms and Complications of Acute Red Throat in Everyday practice)**

**PATIENT INFORMATION SHEET MREC number: 06/MRE06/17 (Version 7a 08 08 07)**

**What is the purpose of this study?** You are being invited 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 out which people with a sore throat get better without problems, and also the few people who get worse or (very rarely) suffer complications. Finding the answer to this important question will be the first step to better targeting antibiotics in the future to those who will benefit, help avoid side effects when antibiotics are not needed, and to reduce 'resistance' resulting from overuse of antibiotics.

**Why have I been chosen, and who can't take part?** Your doctor/nurse thinks you are suffering from a throat infection based on the soreness of your throat and the inflammation (redness) in your throat. Young children and people with severe mental health difficulties cannot take part. At least 30 people from your practice and 18,000 people across the whole country are taking part.

**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 care, 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 who gets complications.
- You will be given a postcard to return to the researchers if your symptoms get worse, you develop a new symptom or you develop a complication (very rare).
- You may also be asked to complete a Diary or a Questionnaire. The diary will tell us about the severity and duration of your sore throat. The Questionnaire will help us see whether patients who have more problems with their sore throat are different from patients whose sore throat settles without problems. The Diary is simple, takes about 3 minutes to complete each day, and has room for up to 14 days entries if necessary. If diaries aren't returned we send a brief questionnaire for you to fill in instead and if necessary a follow-up phone call. The Questionnaire takes about half an hour to fill in and if not returned we may send a reminder and make a follow-up phone call to see if you have any questions about filling it in.

A research assistant is responsible for collecting the data in the study. We will probably not need to get in touch with you again - but may possibly, to clarify some questions if you are filling out the

Diary or Questionnaire. 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?** For the patients who fill in the Diary or the Questionnaire the main disadvantage in taking part is the time involved. 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 in the Diary or Questionnaire (if you fill one out). Your name will not appear on any papers or reports. To keep your information confidential all Diaries and 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 diaries 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 Medical Research Council, coordinated in six sites in England and Wales. Southampton University is coordinating the study locally. It has been approved by the Multi-Centre Research Ethics Committee (application no. 06/MRE06/17) and your Local Ethics Committee. If you have any questions about the study please feel free to ask your Doctor/Nurse or the research team at the number below.

**Consenting.** Thank you for taking the time to read this information sheet and considering participating. If you have more questions you can call the central telephone number (023 8024 1076) and/or think about it at home. If you are happy to participate you can either 1) sign the consent form now then leave the white and green copies at the surgery – the yellow copy is for you to keep OR 2) take the consent form home, sign it and then post the white and green copies in the FREEPOST envelope to the researchers at Southampton.

If you have any queries before you sign the consent form, or at any stage in the study please contact:  
Paula Barratt

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(E-mail P.Barratt@soton.ac.uk telephone 023 8024 1076)

(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 phone lines which provide general information about research

Patient Advice & Liaison Service, Isle of Wight Healthcare NHS Trust, 01983 534850

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