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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)

MORE INFORMATION (see laminated card for **Brief Instructions**)

Thank-you very much for agreeing to take part in this very important research

Your contribution will help to determine whether any specific symptoms or combinations of symptoms in patients with a sore throat are associated with an adverse outcome. This will help us to generate the evidence base to target antibiotics to those who really need them.

Inclusion Criteria

- Previously well subjects aged **16 years and over** with acute illness (**14 days or less**), presenting with **sore throat** as the main symptom, with an abnormal examination of the pharynx.
Please also include patients with a longer illness with recent exacerbation of sore throat for ≤ 14 days (in which case record number of days with exacerbation of sore throat)
- In your opinion competent to understand the study and give consent.

Exclusion Criteria.

- Severe mental health problems (e.g. dementia – unable to consent or complete diary).
- Poor English language skills which would prohibit completion of the patient diary.

Packs

Please select one patient pack (**one clear wallet**). **Documents are coded with ID numbers so please ensure that all documents from 1 wallet are used for the same patient.**

If you run out of packs please contact your local coordinator (Mrs Karen Middleton, E-mail kjm2@soton.ac.uk
Phone 023 8024 1076)

Included in your green folder are credit card sized reminder cards – you may like to stick one on your computer to remind you about the study.

Study outline

Please briefly explain the study to the patient and make sure they have the **Patient Information Sheet**.

We suggest the main points to mention are:

- The study aims to find out if it is possible to predict who gets complications, or suffers prolonged symptoms, following a sore throat (complications are very rare).
- The patient will be treated exactly the same whether entering the study or not.
- Information about the patient's illness will be sent to the researchers and later on a researcher will check the patient's notes to see if they had any complications.
- Clinical information given to the researchers will be anonymised.
- Patients will be asked to sign a consent form. If their illness gets worse they will be asked to post a FREEPOST postcard to the study centre. Some patients will be asked to fill in a diary – it will take a few minutes each evening.
- The study will help Doctors in the future prescribe antibiotics to those most likely to benefit.

Any queries or problems? Call the study manager Paula Barratt on 023 80 24 1076

Study website www.descarte.org

Consent

Please give the patient the triplicate **Consent Form**.

- If the patient has understood the study and is ready to sign immediately then please allow them to go ahead and sign. You post the white copy in the FREEPOST envelope to the researchers at Southampton. The green copy is for your reference and the yellow copy is for the patient to keep.
- If the patient is happy to enter the study, but would like to ask further questions before signing the consent form, explain to them that they can call the central telephone line, think about it at home and then sign the form (you will need to give them the triplicate form and FREEPOST envelope to take home). In this case the patient will need to post the white and green copies to the researchers in the FREEPOST envelope and the researchers will forward the green copy to you.

Once the patient has verbally agreed to take part you may enter their clinical details onto the clinical proforma and submit it to the researchers. As stated in the protocol, the researchers will later dispose of all patient information if a consent form is not received (to account for any patient who initially is happy to take part and takes the consent form home to sign, but for any reason does not return it).

You have chosen to enter patients using paper clinical proformas

Complete the clinical proforma and **post the white copy** back to the researchers in the FREEPOST envelope and keep the green copy for your records.

For the majority of questions please fill in the dots to record your answer. If you make a mistake, please put a cross through the mistake and then fill in the dot representing the correct answer.

Documents

In addition to the **Patient Information Sheet** and **Consent Form** please give the patient the A5 **FREEPOST Postcard** to take home (for posting back to the researchers should their illness progress). If there is a **Diary** in the pack (only present in some packs) please also give this to the patient (+freepost envelope and thermometers) to take home (they are asked to post it back to the researchers once completed).

Your notes

Please record that the patient is entered into DESCARTE and the 8 digit Patient ID number.

Please record any **complications** (as below) or **worsening symptoms** and, if possible, encourage your practice colleagues to record similar details for returning DESCARTE study participants.

otitis media:	duration of pain/degree of inflammation/evidence of fluid
quinsy:	admission and treatment
cellulitis or impetigo:	diameter of the spreading erythema, systemic upset; any impetigo
sinusitis:	duration/purulence/lateral prominence (i.e. if worse on one side) of pain or discharge/'second sickening'

Explanations for terms used on the clinical proforma

Difficulty speaking

Throat is so sore or swollen that words cannot be formed properly, in contrast to laryngeal problems which are characterised by hoarseness.

Cervical glands

Select 'Large (>3cm)' for an enlarged node or confluent/ multiple nodes which together are >3cm.

Runny nose

Select 'yes' for a runny nose or a runny nose causing a sensation of stuffiness, select 'no' for chronic causes of blocked nose (allergies, septal deformities, vasomotor rhinitis etc).

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