What will happen to any samples I give?

The only sample you are being asked to give is a throat swab on the day you join the trial. This will be sent with an anonymised identification code to a central laboratory where it will be tested. Neither you nor your GP will receive any results from this throat swab. In the very unlikely event that the swab does show an harmful result you will be made aware through your GP Practice.

What will happen to the results of the research study?

We will publish the results in scientific journals and present them at scientific meetings. Your details will remain strictly confidential, with no personal information being included in any publications.

Who is organising and funding the research?

The research has been organised by the Primary Care Clinical Trials Unit at Oxford University and is being funded by the National School of Primary Care Research (NSPCR).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by NRES Committee South Central - Oxford B REC Number: **12/SC/0684**

Further information and contact details

Chief Investigator:

Dr Carl Heneghan,

Department of Primary Care

Radcliffe Observatory Quarter,

Woodstock Road,

Oxford,

OX2 6GG.

Thank you for taking the time to read this information sheet

Treatment Options without Antibiotics for Sore Throat (TOAST)

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide if you would like to take part it is important that you understand why we are doing this research and what it would involve for you.

Please take time to read the following information carefully and decide whether or not you wish to take part.

You may like to talk to others about the study. Please ask if there is anything that is not clear or if you would like more information.

Department of Primary Care Health Sciences
Gibson Building. Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG
Tel: +44 (0)1865 617868, Fax: +44 (0)1865289412
Chief Investigator: Dr Carl Heneghan

The Study

What is the purpose of the study?

We want to find out whether a single dose of steroid medication can help people who have a sore throat feel better faster, and reduce the need for them to take antibiotics. It is very common for people to go and see their GP with sore throat (approximately one in ten patients each year). We know that antibiotics are not very helpful for most sore throats, and national guidance recommends that in most people, they should not be prescribed. However, over half of the patients who see their GP will be given antibiotics, which may be contributing to the development of antibiotic-resistance.

We think that a single dose of steroids may be an alternative treatment, which can offer patients relief from their sore throat. We know that steroids reduce swelling in the nose and throat, and they are commonly used in the treatment of similar problems, for example sinusitis and croup. This study will test the use of a steroid called dexamethasone against a placebo to treat a sore throat and will monitor how quickly the symptoms resolve.

Why have I been invited to take part?

We are inviting people to take part who are visiting their doctor to seek medical advice for a sore throat. Your doctor will assess whether you are eligible for the study. In total we are hoping to recruit 510 volunteers for this trial.

Do I have to take part?

It is your decision whether to be part of this study. If you do decide to take part please let your GP or Nurse know today in order to take part in the trial. If you decide to take part you are free to withdraw at any time without giving a reason, and this would not affect the standard of care that you receive in any way.

What happens if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason, withdrawing from the study will not affect your future medical care. The research team will still use the data collected up to your withdrawal unless you tell us at the time that you withdraw that you would prefer us not to.

What happens once the trial has stopped?

Once you have finished the trial you will be looked after as usual by your GP

What if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, the research team will contact you and ask if you wish to continue in the study. If you decide to continue we may ask you to sign an updated consent form. It may be that the new information means that we think it's best to withdraw you from the study, or stop the study altogether, in which case we will let you know and explain the reasons.

What if there is a problem?

If you have any queries about this study then please contact the study co-ordinator Julie Allen on julie.allen@phc.ox.ac.uk or 01865617868.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should firstly contact the study co-ordinator on the details above or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG (email: ctrg@admin.ox.ac.uk).

The University has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which you are provided.

What are the possible disadvantages or side effects of taking part?

Firstly: Your sore throat may not improve after taking the trial medication. Even if you are randomly allocated the corticosteroid medication, it is not yet proven to be an effective treatment for sore throats by itself.

Secondly: There is a small risk of side effects from taking dexamethasone. A short course of corticosteroids usually causes no side-effects. For example, a 1-2 week course is often prescribed to ease a severe attack of asthma and this is usually taken without any problems. Side-effects are more likely to occur if you take a long course of corticosteroids (more than 2-3 months), or if you take short courses repeatedly.

Rare side effects include having an allergic reaction to the dexamethasone, becoming confused with hallucinations or delusions, or very low in mood. Common side effects which are unlikely to have any lasting consequences for you are dyspepsia or heartburn and difficulty getting to sleep.

Thirdly: We are asking you to make a commitment to complete a symptom diary which may take up to 5 minutes every day for 7 days; and receive text messages or telephone calls at 24 and 48 hours after treatment from the trial research team.

What are the possible benefits of taking part?

There are no guaranteed benefits to you from taking part in this study. However, you will be helping research to improve the treatment of sore throats in the future, and potentially give us ways to reduce the unnecessary use of antibiotics in the UK.

Expenses and Payments

You will not be paid for taking part in this research study, but your travel expenses will be paid if you have to make another trip to the GP Practice in order to take part in the trial. Once you complete and return the Symptom Diary to the PC-CTU then you will be sent a £20 gift card to thank you for taking part.

The Medication

What medication will I be taking?

You will receive a single capsule containing either 10mg of a steroid medication called dexamethasone or a similar quantity of placebo. The capsules are identical and neither you nor the doctors or nurses at your practice will know which drug the capsule contains. You stand a 50% chance of receiving either medication.

What is dexamethasone?

The type of steroids used to treat disease are called corticosteroids. They are different to the anabolic steroids which some athletes and bodybuilders may use. Dexamethasone is one type of corticosteroid medication. Corticosteroids are hormones that occur naturally in the body. Amongst other effects, they work to reduce inflammation and swelling, which is thought to be why sore throats are painful. Corticosteroids are regularly used in other infections of the upper airways such as croup and sinusitis. In this trial we are using Dexamethasone because it has been shown to be successful in hospital based clinical trials looking at steroids in sore throat, and because it stays in the body for a longer time than other types of corticosteroid.

What is a placebo?

A placebo is a capsule that contains no active medication. By giving half of our participants a placebo capsule we make sure that our trial does not show benefits simply due to taking a capsule, but shows the effects of taking the dexamethasone medication. The placebo we are using in this trial will look exactly the same as the steroid capsules.

How it works

What will happen to me if I do take part?

You will first be seen by your doctor or nurse in the usual way to assess your sore throat. As part of this visit the doctor or nurse will tell you about the trial and will check to see if you are eligible to take part. They will do this by:

- Going through a check list of symptoms and recording their severity.
- Checking the medications you are on, other medical conditions you have and some basic details about you.
- Doing a routine examination of your throat.

They will then give you this information sheet for you to read to help you decide whether you would like to participate in the trial. You will be given time to think about whether you would like to take part in the trial, you will be able to ring friends or family members if you wish to discuss taking part with them.

If you are interested in taking part you will then go back to see a doctor or nurse who will:

- Give you the opportunity to ask any questions you may have.
- Ask you to sign a written consent form to say you are voluntarily taking part in the trial and you understand what is involved.
- Go through screening procedures. This will include recording your symptoms in more detail, checking your temperature and taking a swab of your throat.
- Provide you with a delayed antibiotic prescription, if your doctor has decided that this would be appropriate, and instructions on how to use this.
- Give you a single dexamethasone or placebo capsule to take immediately.
- Complete online forms about your sore throat symptoms, and show you how to complete either a paper symptom diary when you go home.

This will all take place on the **same day** that you visit the surgery, but may happen later in the day if this is more convenient.

24 and 48 hours later, our research team will contact you at home to ask you about whether your sore throat is feeling better, this will happen via telephone or text. We will also ask you to fill in a paper diary of your symptoms, any medications you take and any visits or calls you make to health services for the next 7 days. You will be shown how to fill in the symptom diary in your appointment with the researcher.

After one month the team at your GP surgery will review your medical notes to check which medications you took, any GP, A and E or hospital visits and any other significant diseases or conditions you may have. You will not be contacted at this point, the GP staff will simply look through your medical notes. After this your participation in the study is complete. You will be sent a short follow up questionnaire after 2 weeks if you do not complete the symptom diary. This will ask you about the first four days after taking the trial medication.

What we will expect from you

By taking part in the trial we would expect you to

- Be available 24 and 48 hours after taking the medication to tell us how you are feeling by telephone or text message
- Complete a diary about your symptoms and the effects of your sore throat for 7 days after taking the medication

Will my taking part in the study be kept confidential?

Yes. If you join the study, some parts of your medical records may be looked at by authorised members of the research team and people checking that the study is being carried out correctly. The information collected for the study will be stored securely in electronic systems with no personal identifiers attached (such as name or address) to which only authorised personnel will have access. We will be collecting your personal contact details to gather some follow-up information for the trial, but as soon as the information has been gathered your contact details will be anonymised.