To be printed onto local headed note paper

TOPPITS

Trial **o**f **P**roton **P**ump **I**nhibitors in **T**hroat **S**ymptoms (**TOPPITS**)

Patient Information Sheet

PART 1

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what taking part would mean for you. Please take time to read the following information carefully, and feel free to talk to others about the study, if you wish. Take some time to consider it carefully before you decide.

- Part 1 tells you the purpose of this study and what will happen to you if you take part
- Part 2 gives you more detailed information about the conduct of the study

Please ask us if there is anything that is not clear.

What is the purpose of the study?
Throat symptoms such as throat clearing, feeling of a lump in the throat, voice changes, discomfort, post nasal drip, throat clearing, dry cough or excess mucus are all extremely common conditions. Doctors believe that these symptoms are sometimes caused when acid from the stomach passes upwards and irritates the upper airway. Doctors thus often treat these throat symptoms using traditional 'heartburn' remedies, most often a treatment called a proton pump inhibitor (PPI). These medicines stop stomach cells from making acid. One common PPI is lansoprazole.

We therefore want to look at lansoprazole to investigate whether it is helpful in improving persistent throat symptoms. A total of 332 patients with persistent throat symptoms will be divided into one of two groups; one group will receive placebo (a dummy capsule) and one group will receive the study medication, lansoprazole.

Why have I been invited to take part in TOPPITS?
You have been invited to take part in TOPPITS because your GP referred you to an Ear, Nose and Throat (ENT) specialist and they have said that you have had throat symptoms for over six weeks and could be eligible for this study.

You may not take part in the study if:

- You are not willing to undergo a video laryngoscopy
- You are currently on acid suppressants, acid neutralizers or alginates and are unwilling to stop using them for 4 weeks before you start the study medication.
- You are pregnant or breast feeding

Do I have to take part?
You do not have to take part, and it is up to you to decide. You can withdraw from the study at any time, without giving a reason, and this will not affect the care that you receive.

What will happen to me if I take part?
People joining the study take two tablets of the study medicine every day for 16 weeks, and come to the hospital clinic twice to see how the throat has responded.

Visit 1 – The TOPPITS clinic
If you have not already been seen by one of the investigators, an appointment will be made for you at the special throat clinic within the next 4 weeks. Prior to this you may be given access to a DVD that explains more about the study at the specialist throat clinic. You will find out more information about the TOPPITS study and any questions you have will be answered. If you would like more time to consider taking part in the study, a second appointment can be arranged for you at a later date.

If you are interested in taking part in the TOPPITS study you will be asked to sign a Consent Form to show your agreement and give your permission.

A member of the clinical research team will carry out a general health examination. They will measure and weigh you and they will take your medical history.

You will then be asked to complete three questionnaires which should take about 5 to 10 minutes. These questionnaires ask about your throat symptoms.

You will also need to have a photograph taken of your throat and voice box with a narrow endoscope after anaesthetic spray. You may have had a similar test – similar cameras are used in all Ear Nose and Throat clinics.

You will then be randomly allocated to receive either 16 weeks' supply of lansoprazole or placebo.

Visits 2 and 3 – Follow-up
An appointment will be made for you at the TOPPITS study clinic 4 months after your first visit. You will be seen by one of the research team and asked to repeat the three questionnaires.

A final appointment will be made for you at the TOPPITS study clinic 8 months later. You will be asked to repeat the three questionnaires again.

We have to do this three times to be able to measure any change in your scores.

Expenses and payments
You will not receive payment or reimbursement of expenses for taking part in this study.

What will I have to do?
You will be expected to take the study medicine two times a day, as directed, every day during the study. You will need to attend hospital visits, when requested to, and to fill in the questionnaires. You should also continue to take any medicines that you are already taking, at the same doses if at all possible. The on-going care you receive for other reasons will not be affected in any way if you take part in this study.

What are the alternatives for diagnosis or treatment?
The current treatments for persistent throat symptoms are traditional 'heartburn' remedies, or hydration with steam, frequent sips, or avoidance of cow's milk dairy produce.

What are the possible disadvantages or risks of taking part?
We want you to be safe in this study at all times, but all medical treatments carry some risk. Lansoprazole is a very safe drug which is used in thousands of NHS patients with stomach problems every month. However, if you react badly to the drug your doctor will be able to change your medication and treat you immediately. If he/she needs to find out which treatment you are taking, this information is available 24 hours a day, seven days a week.

What are the side effects of any treatment that I will receive if I take part?
As with any medicine, the medication used in this study may cause side effects. Some side effects which have been reported are dizziness, vertigo and visual disturbances. Under these conditions the ability to react may be decreased. Other side effects include nausea, stomach ache, constipation and rash.

A standard local anaesthetic spray, applied to the nostrils and throat will be used to reduce the discomfort of the flexible endoscopy. You should not eat or drink for one hour after the procedure to allow time for the numbness in the throat to subside. This will reduce the risk of food going down the wrong way.

If the study doctor feels that it is important to know which medication you are taking (lansoprazole or the placebo), they can get this information at any time.

Harm to the unborn child
To take part in the study, women must not be pregnant or breast feeding. Woman of childbearing age must use adequate contraception.

If you do become pregnant during the course of the study, you must tell your doctor **immediately** so appropriate action can be discussed.

What are the possible benefits of taking part?
We cannot promise the study will help you directly but the information we get from this study will help improve the treatment of people with persistent throat symptoms.

What happens when the research study stops?
When we have answers to the questions in the trial, whether that is at the end of the study or before, we will use the information to give all patients the best possible treatment.

Will my taking part in this study be kept confidential?
All study information, including personal details, will be kept confidential and will not be made public. With your permission, we will let your family doctor (GP) and other healthcare professionals involved in the study know that you are taking part. The study data and your original medical records may be looked at by people who are monitoring or auditing the study, Independent Ethics Committee (IEC) or other regulatory authorities, or the hospital Trusts involved in the study, to make sure that the study is being run correctly. By signing the consent form, you are giving your permission for this to happen. Everyone involved in this study has a duty of confidentiality to the participants and this will be maintained.

PART 2

What if relevant new information becomes available?
If, during the course of the study, new information becomes available, we will tell you about it and discuss whether you should or would like to withdraw from the study. If it is better for you to withdraw, you can do this without giving a reason. This will not affect the care that you receive.

What will happen if I don't want to carry on with the study?
You have the right to withdraw from the study at any time for any reason, and without giving a reason. But we might ask you if you are happy for us to record why you have decided to withdraw. We will also keep the data we have collected on you up to the point of withdrawal.

What if there is a problem?
If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions: **********

If something does go wrong and you are harmed in the course of this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action against The Newcastle upon Tyne Hospitals NHS Foundation Trust, and the normal NHS complaints mechanisms are still available to you.

If you are still unhappy and wish to complain formally, you can do so through the hospital's procedure Patients Complaints Service (PALS) **********

Involvement of the General Practitioner/family doctor (GP)
With your permission, we will let your family doctor (GP) know that you are taking part. Participation in the study will also be noted in your hospital records so that anyone who treats you will know you are taking part in the study.

Who is organising and funding the research?
This study is being funded by the NIHR Health Technology Assessment programme. This body is funded by the UK government to carry out research for the benefit of the NHS and its patients. It is being organised and carried out by a team of researchers based in Newcastle upon Tyne.

What will happen to the results of the research study?
The results of the research study will be published in medical journals, and will be sent to the funder as a report. They may also be presented at medical conferences and shared with other doctors, nurses, patients with persistent throat symptoms. All study data in published articles are anonymous.

Will I be able to find out whether I was receiving lansoprazole or placebo during the study?
Yes – you will be asked at the final study visit whether you would like to be informed what treatment you received during the study. If you do wish to find out the study team will make a note of this and once all data from the study has been analysed you will be contacted by letter and told whether you had received active study drug (lansoprazole) or placebo during the study.

Who is providing the study drug?
A pharmaceutical company (ModePharma) will provide the lansoprazole and the placebo (no drug) to all hospitals involved in the TOPPITS study. Both the lansoprazole and placebo tablets will look identical.

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 interests. This study has been reviewed and given favourable opinion by North East - Sunderland Research Ethics Committee.

Further information and contact details
These are some of the people working on this study. If you have any further questions or would like any further information about the study or the rights of participants, please feel free

to contact them or visit the TOPPITS website www.toppits.co.uk. They are also who you or your doctor should contact in the event of a study-related emergency.

Janet A Wilson – 01912231086

Thank you for your interest in the study, and for taking part, if you decide to do so.