PARTICIPANT INFORMATION SHEET

Helicobacter Eradication Aspirin Trial (HEAT)

You are being invited to take part in a research study. Before you decide if you would like to take part you need to understand why we are doing this research and what it would involve for you. Please take time to read the following information carefully. You may like to talk to others about the study. 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 if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the study?

Aspirin is a valuable drug, often prescribed at low doses to reduce the chance of heart attacks and strokes. However, aspirin can sometimes cause internal bleeding from ulcers. We are trying to find out whether this occurs more in patients who carry the bacteria *Helicobacter (H.) pylori*. This bacteria is present in the stomach of more than half the world's population who usually do not know they have it because it seldom causes symptoms. We are conducting a study to find out whether getting rid of the bacteria with antibiotics reduces the chance of ulcer bleeding.

Why have I been invited?

We are approaching all suitable patients aged 60 or over who are prescribed aspirin on a regular basis (approximately 120,000 people across England). If you think you might like to be involved in this study, please read the rest of this information sheet.

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 return the reply slip to the research team in the envelope provided. You would be 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 will happen to me if I take part?

If you do decide to take part, we will contact you by telephone to make an appointment to see you at your local GP surgery. At this visit, our research nurse will make sure that the study is suitable for you, and answer any questions you might have. You will then be asked to sign a consent form, confirming that you would like to take part in the study and giving us permission to look at your medical records at your GP surgery and from the hospital.

We will ask some questions about your medical history, take some simple measurements (e.g. blood pressure) and then carry out a breath test for *H. pylori.* The breath test is very simple but you need to have had nothing to eat or drink for 6 hours. You will be asked to breathe out into a tube to have your breath collected, then drink the breath-test drink, and 30 minutes later give another breath sample. The test is short but you should probably allow an hour in total for your visit. The breath sample will be sent away for analysis, and you will be told by post whether it was positive or negative.

If the breath test is positive you will randomly (50-50 chance) be given either one week of antibiotic or one week of placebo (dummy) treatment, which will be sent to you by post. We will contact you by telephone to find out if you have received and started the treatment, and whether you have any problems. We will also send you two forms with prepaid envelopes. One form is for you to record details of your treatment and any effects you had from it. The second form is for you to send to us if you ever go to hospital or if you change address.

The tablets you will be asked to take may contain lactose, but only in small amounts. Therefore if you have intolerance to lactose, you should consider this before taking part. Likewise, the tablet-coatings will

contain gelatine of animal origin, so you would need to consider this if you are unable to eat such products.

If your breath test is negative you will be sent a letter to inform you of this result and you will not need to take any further part in the study.

Most people involved in the study will not have to attend any further visits. If for any reason you have to go into hospital, we may ask you to come for a repeat breath test, depending on the reason for your admission. We will contact you once a year to find out if this has happened. In addition to this, a one in 10 sample of patients who test positive for *H. pylori* and are treated (approximately 1,000 patients) will be asked to come back to their local GP practice for another breath test at the end of the study, just to check that the treatment has worked as it should.

The study as a whole will last for about three years, but your involvement may be shorter. When the research is finished we will let you know the results of the research.

Expenses and payments.
You will not be paid for taking part in this research study, other than payment for travel expenses; please inform the study nurse when you attend your GP practice for your trial visit if these are required.

What are the possible disadvantages or side effects of taking part?
The breath test is a very simple test which is already routinely used by GPs. You may find it inconvenient that you cannot eat, drink (other than water) or smoke before you come for your appointment, but the breath test itself carries no risk.

If you are found to be positive for *H. pylori* and receive the antibiotic treatment, this will be prescribed according to current normal guidelines. As with all medicines, there may be some side effects. Occasionally, the treatment may give a slight metallic taste in your mouth. This is harmless and is a sign the treatment is getting into your body. Other common side effects you may experience include tummy upsets (diarrhoea, constipation, nausea, vomiting, dyspepsia, abdominal pain/discomfort), skin rash, itching, headache, dizziness, sore mouth, fatigue, drowsiness, poor appetite, darkening of urine.
One of the drugs used interacts with alcohol and may make you feel extremely unwell, so **you must not drink alcohol during the week of treatment**.

If you receive placebo treatment, you are less likely to get side effects but you will still carry the *H. pylori* bacteria. However, this does not mean that you will experience any more symptoms than you did before the breath test results. At the end of the study we will tell you which treatment you had and whether the study showed any benefit from antibiotic treatment so that you can decide whether to have treatment at this stage.

What are the possible benefits of taking part?
We do not know if the treatment will be successful. People who receive antibiotics may benefit if the idea behind the study is correct but on the other hand may get some side effects. People receiving placebo treatment will continue to carry the bacteria during the study but will be able to decide whether to have antibiotics later when the results of the study are known.

What if there is a problem?
If you feel unwell whilst taking the study treatment, please contact your GP. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. All information which is collected about you during the course of the research will be stored securely and kept strictly confidential. Only trained members of the research team and individuals from regulatory authorities (people who check that we are carrying out a study correctly) will have access to your records.

This completes PART 1.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

PART 2

What if new information becomes available?
Sometimes we get new information about the treatment being studied. If this happens, the research team will write to 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.

If new information becomes available we may consider that you should withdraw from the study, or if the study is stopped for any other reason, we will let you know and explain the reasons.

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, but the research team will use the data collected up to your withdrawal.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to your GP or nurse, who will do his/her best to answer your questions. You can also contact the main investigator of the study in your region, Professor Greg Rubin, or the Trial Coordinator (Tel: 01642 615600). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the clinic, your GP or your local Patient Advice and Liaison Service (PALS) Office.

In the event that something does go wrong and you are harmed during the research due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Nottingham (the sponsor of this study) but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

Will my taking part in the study be kept confidential?
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 encrypted format in electronic systems, to which only authorised personnel will have access.

What will happen to any samples I give?
The breath samples are the only samples you will give and this will be discarded following the breath test analysis.

What will happen to the results of the research study?
We will publish the results in scientific journals and present them at scientific meetings. This may not occur until some time after the research has finished. Your details will remain strictly confidential.

Who is organising and funding the research?
The research has been organised by researchers at the University of Nottingham and is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme.

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 East Midlands - Leicester Research Ethics Committee.

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

Contact for queries: If you have any queries about this study, you can contact the Trial Office on 01642 615600 or enquiries@nyren.co.uk.