Patient letter of invitation

Date as postmark

Dear

You are invited to attend a review appointment at my outpatient clinic (see enclosed appointment card) for your reflux (heartburn/regurgitation) symptoms.

I am writing to let you know that **<<*Hospital*>>** is part of a large national study funded by the NHS to look at the different types of treatment for reflux. As someone who is taking medication for their reflux symptoms, you may be eligible for the study.

I have included two patient information leaflets about the study. The first explains in further detail why the study is being done and the second explains what would happen if you were eligible to join the study. I would be most grateful if you would take the time to read through the information. There will be the opportunity to discuss the study in more detail during your appointment.

If you would like any further information about the trial please call the trial office directly on 01224 000000.

Yours sincerely

<<*Consultants name*>>
<<*Consultants position*>>
Enc.

The

REFLUX

Trial

A STUDY OF GASTRO-OESOPHAGEAL REFLUX DISEASE

PATIENT INFORMATION LEAFLET

1. WHAT IS THE STUDY ABOUT?

This hospital is one of several centres throughout the UK that are taking part in a study to find out the best way to treat people who suffer from heartburn and reflux. This problem is usually refereed to as gastro-oesophageal reflux disease (GORD).

What is gastro-oesophageal reflux?

Gastro-oesophageal reflux is the term used to describe a back-flow of acid from the stomach into the swallowing tube, the oesophagus. Gastro-oesophageal reflux occurs when the valve at the lower end of the oesophagus (next to the stomach) does not work properly. Almost everyone experiences gastro-oesophageal reflux at some time. The usual symptom is heartburn, an uncomfortable burning sensation behind the breast bone that often occurs after a meal. For some people, reflux can become frequent and serious enough to be regarded as a disease. It is when it reaches this point that it is recognised as being the medical condition known as gastro-oesophageal reflux disease (GORD).

What is the purpose of the study?

The two main treatments routinely used in the National Health Service (NHS) to treat GORD are medication and surgery.

At present we do not know whether medical treatment (drugs in the form of tablets) or surgical treatment is better for treating persistent symptoms of reflux. The main purpose of this study is to find out which form of treatment is best.

This hospital is one of several centres throughout the UK taking part in this study. As a person who is taking medication for their GORD symptoms, you may be eligible for the study. We plan to involve around 1200 people who suffer from persistent symptoms of reflux.

What are the advantages and disadvantages of the two types of treatments being compared?

*The advantages of **medical treatment** are:*

- it is effective in reducing symptoms, if there are any
- it does not require hospitalisation or time off work.

*The disadvantages of **medical treatment** are:*

- it has to be given indefinitely, and may occasionally cause side-effects such as headaches, rash, muscle and joint pain and stomach upsets
- it may impair the normal functions of stomach acid in digesting food and controlling bacteria. It should be remembered that in GORD, acid production by the stomach is usually normal; it simply gets into the wrong place, i.e. the oesophagus.

*The advantages of the **surgical operation** are:*

- it corrects the underlying cause of the problem, namely the faulty valve
- it preserves the normal acid production of the stomach
- it greatly reduces the need for lifelong medication.

*The disadvantages of the **surgical operation** are:*

- it requires one to three days in hospital and approximately two to six weeks off work
- it may cause temporary difficulty in swallowing solids, a feeling of fullness after eating and a change in bowel habits
- it may occasionally fail to abolish the symptoms of reflux
- as with all surgery, it is associated with a risk, albeit a very low risk, of operative death or serious complications.

What happens next?

Your doctor(s) will assess whether you are eligible for the study. If so, he/she will give you further information and ask if you would like to take part.

Who is organising the study?

The study is being funded by the NIHR Health Technology Assessment Programme.

Contact for Further Information

REFLUX Trial Office
Health Services Research Unit
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD
Tel. 01224 000000 Fax: 01224 554580
Email: reflux@hsru.abdn.ac.uk

Thank you for reading this

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you might want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW

The REFLUX Trial

A STUDY OF GASTRO-OESOPHAGEAL REFLUX DISEASE

PATIENT INFORMATION LEAFLET

2. WHAT HAPPENS IF I JOIN THE STUDY?

Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends or relatives if you wish. Ask us if there is anything you don't understand or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The two main forms of treatment routinely used in the NHS to treat GORD are medication and surgery. At present we do not know whether medical treatment (drugs in the form of tablets) or surgical treatment is better for treating persistent symptoms of reflux. The main purpose of this study is to find out which form of treatment is best.

To find out which is the best way of treating people with GORD we need to make comparisons between groups of people receiving medication or surgery. In this study, people are allocated, by a computer, to one of two different treatment groups: (1) medical treatment, or (2) surgery. The computer selects people to these two groups by chance (this is called randomisation). This is done so that we can be sure that both groups will include the same mix of people – male or female, older or younger – and the only difference between the groups is the treatment they will receive.

Half the people participating will receive long-term medical treatment and the other half will receive an operation. Those in the medical treatment group will continue with medication to control their symptoms. For many this is likely to be the same type of tablets as prescribed previously, but for some people, other tablets may be tried to improve symptom control. Those in the surgery group will have an operation performed by an experienced surgeon, using 'key-hole' surgery. In this, the upper part of the stomach is wrapped around the lower end of the oesophagus. This reinforces the 'valve' between them aiming to stop the reflux.

What will happen if I join the study?

- It is up to you to decide whether or not you would like to take part in the study. If you do decide to take part you will be asked to sign a consent form and fill in a questionnaire.
- You will be sent questionnaires by post, one after about 6 months and another 9 months later, which will take about half an hour to complete. Contact may continue for some years after that. You are free to decline to answer any of our questions without giving a reason at any time.
- Information relating to the treatment of your reflux symptoms may be collected from your medical notes.

What are the advantages and disadvantages of the two types of treatments being compared?

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What are the possible benefits of taking part?

We hope that the treatment you receive will control your GORD symptoms. However, this cannot be guaranteed. The information we will get from this study may help in the future to provide better treatment for patients with GORD.

We want to reassure you that:

- Your involvement in the study is entirely voluntary.
- You are free to withdraw at any time and this would not affect your current of future medical treatment. Although we do not expect participation to affect private medical insurance, if you do have insurance, please check with the company before agreeing to take part in the study.
- All information collected for the study will be treated as confidential and used only for the purpose of the study.
- All people taking part will be kept informed about the study and will be sent a summary of the results. The results of the study will be published in medical journals. Participants will not be identifiable in any of the study reports.
- Both forms of treatment are in common use in the NHS. You will not have to undergo any tests or procedures that are not part of the routine management of GORD.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you have any cause to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms are available to you.

Contact for Further Information

REFLUX Trial Office
Health Services Research Unit
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD
Tel. 01224 000000 Fax: 01224 554580
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