The REFLUX Trial

A STUDY OF GASTRO-OESOPHAGEAL REFLUX DISEASE

PATIENT INFORMATION LEAFLET

3. WHAT HAPPENS IF I CHOOSE MY TREATMENT WITHIN THE STUDY?

- THE PREFERENCE STUDY -

Before you decide whether to take part in the preference study, 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 main purpose of this study is to find out which of the two main forms of treatment routinely used in the NHS to treat Gastro-oesophageal Reflux Disease, GORD (taking medication or having an operation) is better for treating persistent symptoms of reflux.

Comparisons can be made about these treatments in two different ways. The first, which was described in the second patient information leaflet, compares groups of people who have no strong preference for the two treatment groups and are willing to be allocated at random to one of the groups. The second is to look at comparisons between groups of people who **choose** their own preferred treatment from one of the two treatments being studied.

If you have chosen to continue with medication, it is likely that you will continue taking the same type of tablets you have previously been prescribed, although other tablets may be tried to help improve symptom control.

If you have chosen to have surgery, you will have an operation 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.

Including eligible people who have a strong preference for a particular treatment, allows the study to be completely representative of all people who suffer with GORD.

What will happen if you join the preference study?

- If you 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, at specific time intervals after joining the study, 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 the questions without giving a reason at any time.
- If you do join the study, you are still free to withdraw from it any time without giving a reason.
- Information relating to the treatment of your reflux symptoms may be collected from your medical notes.

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.
- All information collected for the study will be treated as confidential and used only for the purpose of the study.
- We will inform your GP that you are taking part.
- 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 554196 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

Participant Study No

Preference Consent Form

Copy 1
Participant's Copy to Keep

I have:

- Discussed the study with

	Yes	No
• Been given the Information Leaflets about the study	☐	☐
• Received satisfactory answers to questions	☐	☐
• Been given satisfactory information about the study	☐	☐

I understand that:

- I have chosen to have surgery / continue with medication* for the treatment of my reflux symptoms (*delete as appropriate)
- I will be sent questionnaires at specified time intervals after starting the study
- I may be approached to find out how I am, for some years after starting the study
- Information related to treatment of reflux may be collected from my medical notes
- My family doctor will be notified that I am taking part in the study
- I am free to withdraw from the study at any time without having to give a reason
- If I withdraw, this will not affect my future care

I agree to take part in the study

Signature of participant

Name (in block capitals)

Date

I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved

Signature of researcher

Date

REFLUX Trial Office, Health Service Research Unit (Flea), University of Aberdeen, Foresterhill, ABERDEEN AB25 2ZD
Tel: 01224 000000 Fax: 01224 554580 Email: REFLUX@abdn.ac.uk

The REFLUX Trial

Participant Study No

Preference Consent Form

Copy 2
To Return to The REFLUX Trial Office

I have:

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	Yes	No
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