April 2003



Issue No. 5

WELCOME TO THE FIFTH ISSUE OF THE REFLUX NEWSLETTER

This is the fifth issue of the REFLUX Trial Newsletter. The main developments within the trial since the last newsletter have included:

- the NHS R&D HTA Programme have agreed to extend participant recruitment until May 2004
- all 21 centres are now established and have a research nurse in post
- the organisation of the fourth collaborator's meeting

If you have any news, events or other information you think should be included in future newsletters, please contact the REFLUX Trial Office on 01224 554196 or email reflux@hsru.abdn.ac.uk.

TRIAL PROGRESS REPORT

Extension of trial recruitment

We are pleased to announce that our application to the NHS R&D HTA programme to extend the recruitment phase of the trial has been successful. We have been awarded funding to extend recruitment by a further 12 months until 31 May 2004. Consequently, we are in the process of contacting all centres regarding a continuation of research nurse subcontracts for this period.

This extension of recruitment will also result in an overall increase of the trial duration by 12 months (end 31 May 2006), to allow for complete follow-up data to be collected.

Trial progress and recruitment

We now have 21 centres participating in the trial and all but 3, who have recently recruited a research nurse, are now recruiting participants into the trial. Recruitment is continuing to improve and we now have a total of 170 participants recruited to the **randomised** group (88 medical, 82 surgical) of the trial and 202 participants to the **preference** group (87 medical, 115 surgical), as of 7 March 2003.

| Centre | Pts randomised (start date) | Centre | Pts randomised (start date) | Centre | Pts randomised (start date) |
|-------------|-----------------------------|----------------|---------------------------------|----------------|---------------------------------|
| Aberdeen | 55 (Mar'01) | Hull | 10 (Aug'01) | Portsmouth | 14 (Sep'01) |
| Belfast | 14 (Feb'02) | Inverness | 7 (Jan'02) | Salford | 1 (Apr'02) |
| Bournemouth | 4 (May'02) | Leeds | Awaiting 1 st clinic | Stoke-on-Trent | 1 (Mar'03) |
| Bristol | 1 (Dec'02) | Leicester | 0 (Apr'02) | Swansea | 8 (May'02) |
| Bromley | 3 (Dec'02) | Lon -St Mary's | 13 (Mar'01) | Telford | Awaiting 1 st clinic |
| Edinburgh | 9 (May'02) | Lon-WhippsX | 1 (Aug'02) | Yeovil | 12 (Sep'02) |
| Guildford | 9 (May'02) | Poole | 8 (Jan'02) | York | Awaiting 1 st clinic |

We hope that the extension to the recruitment period will enable us to reach the respective recruitment target of 391 (randomised) and 424 (preference) participants. In order to achieve this, each centre will need to recruit 20 participants to the randomised group.

GENERAL TRIAL NEWS: PUBLISING THE TRIAL

The challenge of identifying and recruiting patients continues and we are constantly exploring ways in which to publicise and promote the trial to maximise recruitment. Although we have implemented inhouse publicity (posters/flyers) and/or local advertisements at many centres, the Trial Office welcomes any ideas or suggestions from our collaborators on methods of promoting the trial.

In addition to the above, we are also promoting the trial through attendance at relevant meetings. To date these have included:

SIGN: The Scottish Intercollegiate Guidelines Network (SIGN) is responsible for the development and dissemination of clinical guidelines throughout NHS Scotland. We attended the clinical launch meeting for a new national guideline on the investigation and management of dyspepsia, whose multidisciplinary audience included general practitioners, gastroeneterologists, upper GI surgeons and a range of healthcare professionals. A poster together with background information/flyers were used to promote the trial.

BSG: We attended the British Society of Gastroenterology meeting in Birmingham in March 2003. This provided an opportunity for us to meet with our collaborating gastroenterologists, to update them on the progress of the trial, increase motivation and resolve any local problems. A similar exercise is planned for the Association of Surgeons of Great Britain & Ireland meeting in Manchester in May 2003.

THE FOURTH COLLABORATOR'S MEETING

Friday 23 May 2001

at

MRC Clinical Trials Unit 222 Euston Road LONDON

14:00 - 16:30

The agenda, together with all other meeting documents, will be sent out to the REFLUX Trial collaborators in early May

future meetings . . future meetings . . future meetings

Steering Group: In conjunction with the Collaborators meeting on 23 May 2003, London

ASGBI: A Trial Office representative will be attending the Association of Surgeons of Great

Britain & Ireland meeting in Manchester in May 2003.

If you would like trial information for hospital colleagues or any further information about the trial, please contact the Trial Office on 01224 554196.