The place of minimal access surgery amongst people with gastro-oesophageal reflux disease (GORD) - a UK collaborative study

Submission date 25/04/2003	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 25/04/2003	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 24/02/2014	Condition category Digestive System	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website http://www.abdn.ac.uk/hsru/hta/reflux.shtml

Contact information

Type(s) Scientific

Contact name Prof Adrian Grant

Contact details

Health Services Research Unit University of Aberdeen Polwarth Building Foresterhill Aberdeen United Kingdom AB9 2ZD +44 (0)1224 553908 a.grant@adn.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers HTA 97/10/03

Study information

Scientific Title

Acronym

REFLUX

Study objectives

Study hypothesis amended as of 09/08/2007 (Please note that these amendments reflect errors in information provided at time of registration):

1. To evaluate the clinical effectiveness, cost-effectiveness, and safety of a policy of relatively early laparoscopic surgery compared with continued medical management amongst people with Gastro-Oesophageal Reflux Disease (GORD) judged suitable for both policies.

2. To explore factors which may influence the relative performance of the two policies, such as patient preference, surgeon experience, pre-enrolment symptoms and signs, the underlying pathology, the type of operative procedure used or choice of therapy, and the time since surgery.

3. To explore the impact that various policies for using laparoscopic surgery would have on the NHS and society. Multi-centre, pragmatic randomised trial (with parallel, non-randomised preference groups), Economic evaluation. Setting: Secondary care provided by gastro-enterologists and surgeons.

Previous study hypothesis:

1. To evaluate the clinical effectiveness, cost-effectiveness, and safety of a policy of relatively early laparoscopic surgery compared with continued medical management amongst people with gastro-oesophageal reflux disease (GORD) judged suitable for both policies.

2. To explore factors which may influence the relative performance of the two policies, such as patient preference, surgeon experience, pre-enrolment symptoms and signs, the underlying pathology, the type of operative procedure used or choice of therapy, and the time since surgery.

3. To identify the proportion and number of patients with GORD managed within the NHS for whom laparoscopic surgery could be recommended.

4. To explore the impact that various policies for using laparoscopic surgery would have on the NHS and society.

Multi-centre, pragmatic randomised trial (with parallel, non-randomised preference groups), Primary care based descriptive population study, Economic evaluation. Setting: (A) Secondary care provided by gastro-enterologists and surgeons (B) General practice (C) Combination of (A) and (B).

More details can be found at http://www.hta.ac.uk/1134

Please note that, as of 09/08/2007, the target number of participants has been amended from 357 to 810.

Please note that, as of 11/01/2008, the anticipated start and end dates of this trial have been updated from 01/10/1999 and 31/05/2011 to 01/06/2000 and 30/09/2006, respectively. The anticipated end date of this trial provided at time of registration was 30/09/2004.

An extended follow-up study of this trial started in May 2007 (HTA ref: 97/10/99).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Medical Research Ethics Committee for Scotland and Local Research Ethics Committees.

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Gastro-oesophageal reflux disease

Interventions

Laparoscopic surgery vs continued medical management

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Primary outcome measures amended as of 09/08/2007:

Cost and outcome measurement (assessed through annual questionnaires):

1. Primary: disease-specific quality of life, health-related quality of life (the EuroQoL [EQ-5D]

questionnaire and the 12-item Short Form health survey [SF-12]) and NHS costs.

2. Treatment preferences and attitudes to surgery and medical management.

3. Indices of differential cost effectiveness with economic modelling.

Previous primary outcome measures: Cost and outcome measurement: 1. Primary - NHS costs and health-related quality of life (EQ5D and SF12) secondary - patient costs, disease specific HRQL, treatment changes, side effects and complications. 2. Prevalence PPI for GORD (>12 months); treatment preferences and attitude to surgery. 3. Indices of differential cost effectiveness and economic models of NHS uptake of minimal access surgery.

Secondary outcome measures

Added as of 09/08/2007: The following are assessed through annual questionnaires: 1. Patient costs 2. Treatment changes 3. Side effects and complications

Overall study start date

01/06/2000

Completion date

30/09/2006

Eligibility

Key inclusion criteria

Inclusion criteria amended as of 09/08/2007 (Please note that these amendments reflect errors in information provided at time of registration):

Long-term proton pump inhibitor (PPI)-treated GORD patients suitable for surgical or medical secondary care management

Previous inclusion criteria:

1. Long-term proton pump inhibitor (PPI)-treated GORD patients suitable for surgical or medical secondary care management

2. All PPI treated GORD patients in General Practice

Participant type(s) Patient

Age group Not Specified

Sex Both

Target number of participants 810

Key exclusion criteria Added as of 09/08/2007: Specific contraindications to surgery. Date of first enrolment 01/06/2000

Date of final enrolment 30/09/2006

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Health Services Research Unit Aberdeen United Kingdom AB9 2ZD

Sponsor information

Organisation Department of Health (UK)

Sponsor details Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type Government

Website http://www.dh.gov.uk/en/index.htm

ROR https://ror.org/03sbpja79

Funder(s)

Funder type Government

Funder Name NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	cost-effectiveness results	01/09/2008		Yes	No
<u>Results article</u>	intial results	15/12/2008		Yes	No
<u>Results article</u>	results	14/07/2009		Yes	No
Results article	results	22/03/2010		Yes	No
<u>Results article</u>	results	18/04/2013		Yes	No
<u>Results article</u>	results	01/06/2013		Yes	No