ISRCTN15517081 https://doi.org/10.1186/ISRCTN15517081

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 24/02/2014	**Condition category** Digestive System	

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

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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
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Sponsor information

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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?
Results article	cost-effectiveness results	01/09/2008		Yes	No
Results article	intial results	15/12/2008		Yes	No
Results article	results	14/07/2009		Yes	No
Results article	results	22/03/2010		Yes	No
Results article	results	18/04/2013		Yes	No
Results article	results	01/06/2013		Yes	No