A prospective randomised comparison of laparoscopic anterior versus posterior partial fundoplication in patients with gastrooesophageal reflux disease

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/09/2003		☐ Protocol		
Registration date 12/09/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 22/08/2011	Condition category Digestive System	[] Individual participant data		
ZZ/U0/ZUII	Didestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0059103687

Study information

Scientific Title

Study objectives

To prospectively compare laparoscopic anterior versus posterior partial fundoplication in patients with gastro-oesophageal reflux disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the South Sheffield Research Ethics Committee

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

Health condition(s) or problem(s) studied

Gastro-oesophageal reflux disease (GORD)

Interventions

Comparison of laparoscopic anterior versus posterior partial fundoplication.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Dysphagia
- 2. Reflux control

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/10/2001

Completion date

30/09/2003

Eligibility

Key inclusion criteria

100 patients with gastro-oesophageal reflux disease.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

- 1. Previous anti-reflux surgery
- 2. Other concomitant disease being operated at the same time, e.g., gallstones
- 3. Aged less than 18 or greater than 75 years

Date of first enrolment

01/10/2001

Date of final enrolment

30/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

STH NHS Trust

Sheffield United Kingdom S10 2JF

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

Sheffield Teaching Hospitals (Central Campus) (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	results	01/07/2010		Yes	No