

Total or a posterior partial fundoplication in the treatment of gastroesophageal reflux disease (GERD)

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
15/03/2010	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
10/03/2011	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
04/07/2011	Digestive System	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Total or a posterior partial fundoplication in the treatment of gastroesophageal reflux disease (GERD): results of a randomised trial after two decades of follow up

Study objectives

Differences in side effect and reflux control between open fundoplication total or partial, after 18 years of follow up of a earlier randomised controlled trial (RCT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration - please note that this is the follow-up of an RCT.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gastroesophageal reflux disease (GERD)

Interventions

Surgery for GERD, total nissen or partial fundoplication. Please note that this is the follow-up for a RCT performed 20 years ago; the mean follow up has now reached 18 years. During these years 26% had died and 16% were unable to trace for follow up. Symptom outcomes were assessed by the use of validated self-reporting questionnaires.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Reflux control after 18 years
2. Side effects like gas bloat, dysphagia

Key secondary outcome(s))

Number of recurrences and reoperations

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Aged from 18 to 75 years, either sex
2. Established gastroesophageal reflux referred for surgical treatment in the beginning of 1990

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

1. Pregnant
2. No possibility of compliance in the study protocol
3. Addict
4. Unable to understand the circumstances or the RCT information

Date of first enrolment

01/01/1990

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Sweden

Study participating centre

Per Dubb gatan

Göteborg

Sweden

413045

Sponsor information

Organisation

Sahlgrenska University Hospital (Sweden)

ROR

<https://ror.org/04vgqjj36>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sahlgrenska University Hospital (Sweden) - Department of Surgery

Results and Publications

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	01/05/2011		Yes	No