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

Submission date 15/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/03/2011	**Overall study status** Completed	
Last Edited 04/07/2011	**Condition category** Digestive 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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
Number of recurrences and reoperations

Overall study start date
01/01/1990

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
137

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)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.sahlgrenska.se

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sahlgrenska University Hospital (Sweden) - Department of Surgery

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	01/05/2011		Yes	No