

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

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

**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**

Per Dubb gatan

Göteborg

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413 45

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cecilia.engstrom@surgery.gu.se

**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?
<a href="#">Results article</a>	results	01/05/2011		Yes	No