The SphynX trail: a randomised clinical trial that compares the outcome of endoluminal fundoplication with EsophyX* to laparoscopic Nissen fundoplication for GERD

Published: 08-01-2008
Last updated: 09-05-2024

To compare the outcome of endoluminal fundoplication with Esophyx* to laparoscopic Nissen fundoplication for GERD in selected patient population.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON31384

Source
ToetsingOnline

Brief title
SphynX trial

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
Gastroesophageal reflux, heartburn, reflux disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endoluminal EsophyX fundoplication, gastroesophageal reflux disease, laparoscopic Nissen fundoplication

Outcome measures

Primary outcome

Percentage of patients with objective normalization of acid exposure, without

suffering form severe dysphagia at 6 months.

Secondary outcome

Percentage of patients free from PPI*s

Quality of Life (QoL) and GERD related QoL (GERD-HRQoL) and esophageal symptoms

(OES18-score)

Percentage of patients with resolved, improved, unchanged and worsened symptoms

(Visick grade)

Prevalence of esophagitis

Pressure of the Lower Esophageal Sphincter

Percentage acidic, weakly acidic and gas reflux

Total costs

Study description

Background summary

GERD refractory to acid suppression, with a documented relation between symptoms and reflux episodes, is a well accepted indication for antireflux

surgery. Laparoscopic Nissen fundoplication is the current golden standard for the invasive therapy for GERD. Endoluminal fundoplication (EsophyX*) may be is an endoscopic alternative for this procedure. In selected patients, this procedure has potential benefits. The technique does not require opening of the abdominal cavity, minimizing chances of complications like intra-abdominal damage. The new treatment reduces invasiveness, when compared to laparoscopic Nissen fundoplication. This results in less post-operative pain, less morbidity, better cosmesis and shorter hospitalization. Moreover, sick leave from paid work is shorter after the EsophyX* procedure. These advantages will reduce total costs compared to the conventional procedure. The outcome of endoluminal fundoplication has not yet been compared to the outcome of laparoscopic Nissen fundoplication. This needs to be evaluated to make the right therapeutic decisions for future GERD patients.

Study objective

To compare the outcome of endoluminal fundoplication with Esophyx* to laparoscopic Nissen fundoplication for GERD in selected patient population.

Study design

Randomized, blinded clinical multicentre trial

Intervention

After randomization, eighty patients will undergo endoluminal EsophyX* fundoplication en will be compared to eighty patients who will undergo laparoscopic Nissen fundoplication

Study burden and risks

Similar to all patients that may have an indication for antireflux surgery, the patients that participate will undergo a preoperative upper endoscopy, short manometry and 24-hr pH-impedance study. Patients will be asked to fill out questionnaires before surgery (15 min), both on acid suppressing drugs and after stopping acid suppressing drugs in preparation of the preoperative investigations. These questionnaires will register general quality of life, GERD related QoL and esophageal symptoms. Patients will register medication use in a diary up to thirty days after surgery. One month after surgery, patients will be asked to fill out a short questionnaire (5 min) to register esophageal symptoms. Three, six and twelve months after the operation, the participants will be asked to fill out the questionnaires on general quality of life, GERD related QoL and esophageal symptoms (15 min). These questionnaires are as short as possible tot reduce the burden for the patients.

Six months after surgery upper endoscopy, short manometry and 24-hr

pH-impedance study will be repeated. All these investigations are safe and complications are rare. The department of surgery of the UMC Utrecht has conducted three large follow-up studies, investigating the subjective and objective results of Nissen fundoplication in a similar way. This research has demonstrated that the postoperative complaints reported by patient do not correlate with reflux episodes. Therefore, objective follow-up is essential to compare the outcome of the new procedure to the current golden standard. This will result in better therapy choices for future patients. The postoperative investigations will be similar to the previously mentioned studies. These investigations are a considerable burden for the patients, but in our experience, patients are willing to undergo these additional tests.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Perseverance of reflux related complaints for over 6 months despite of double dose PPI use (>= 40 mg omeprazole / 24 hours or comparable therapy) and/or refusal of taking lifelong antireflux medication.
- Patients without a diaphragmatic hernia or a sliding hernia of max. 2 cm (endoscopically measured distance from Z-line and impression of the diaphragm).
- Pathological ambulatory 24 hour pH test (upright acid exposure > 8.4%, supine acid exposure > 3.4 % and/or total acid exposure > 5.8% and symptom association probability (SAP) > 95%)
- Age: 18-65 years
- Healthy patients with no disease outside of the surgical process and patients with mild to moderate systemic disease caused by the surgical condition or by other pathological processes, medically well-controlled (American Society of Anaesthesiologists classification of preoperative risk 1 or 2)

Exclusion criteria

- Patients with a diaphragmatic hernia other than of the sliding type and / or larger than 2 cm (endoscopically measured).
- Grade C and D esophagitis (Los Angeles classification).
- Histologically proven long-segment Barrett*s esophagus (>2 cm).
- Patients with severe objectified esophageal or gastric motility disorder.
- Patients with a history of esophageal- or gastric surgery.
- Patients with contraindications for undergoing a laparoscopic Nissen fundoplication or endoluminal fundoplication with Esophyx*, for example esophageal stenosis, esophageal stricture, portal hypertension, esophageal varices or diverticulae, active gastro-duodenal ulcer, previous Enteryx, Gatekeeper or Stretta treatment.
- Patients with a psychiatric disease or other conditions making them incapable of filling out the questionnaires or completing the objective follow up tests.
- Pregnant women.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Single blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17954.041.07