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The SphynX trail: a randomised clinical trial comparing the outcome of endoluminal fundoplication with EsophyX™ to laparoscopic Nissen fundoplication for refractory gastro-esophageal reflux disease (GERD)

Submission date 17/02/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/02/2008	**Overall study status** Completed	
Last Edited 26/02/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.esophyx.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07-214

Study information

Scientific Title

Acronym
SphynX

Study objectives
Endoluminal fundoplication with Esophyx™ will not be less effective than laparoscopic Nissen fundoplication, expressed as the percentage of successful procedures, based on the patient's opinion at six months after surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent central medical ethics committee of the University Medical Center Utrecht has approved the study protocol. Date of approval: 08/01/2008 (EC ref: 07-214; CCMO ref: 1795404107)

Study design
Randomised non-inferiority multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Gastro-esophageal reflux disease

Interventions
Endoluminal fundoplication with EsophyX™ versus laparoscopic Nissen fundoplication.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Effectiveness will be expressed as the percentage of successful procedures, based on the patient's opinion at six months after surgery (Visick grading). Visick classification: grade I: No symptoms, resolved; grade II: Mild occasional symptoms easily controlled, improved; grade III: Mild symptoms not controlled, unchanged; grade IV: Not improved, worsened. Success will be defined as grade I or II and failure will be defined as grade III or IV.

Secondary outcome measures
1. Success expressed as the percentage of patients with normalisation of acid exposure on pH metry, minus the percentage of patients needing reintervention (dilatation or re-operation) for troublesome dysphagia at six months

Definition of objective normalisation of acid exposure:
The combination of the following:
a. Upright acid exposure <8.4%
b. Supine acid exposure <3.4 %
c. Total acid exposure <5.8% on post-operative 24-h pH-monitoring
The presence of troublesome dysphagia will render the procedure unsuccessful.

2. Percentage of patients free from PPIs at three and six months
3. Quality of Life (QoL) assessment: Visual analogue scale [VAS] score, the 36-item Short Form health survey (SF-36) and EuroQol (EQ-5D) at three and six months
4. Impact of reflux symptoms on QoL: The Gastro-Oesophageal Reflux Disease Health-Related Quality-of-Life scale (GORD-HRQoL) at three and six months
5. Esophageal symptoms: OES18 score at three and six months
6. Prevalence of esophagitis on upper endoscopy at six months
7. Cost-effectiveness expressed as costs per successfully treated patients and incremental costs per Quality Adjusted Life Year gained at six months

Overall study start date
01/01/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. GERD patients of eight Dutch hospitals with reflux symptoms persisting for over 6 months despite double dose of Proton Pump Inhibitor (PPI) (>40 mg omeprazole/24 hours or comparable therapy) and/or patients who refuse or do not tolerate to take acid suppressing

drugs for life.
2. Documented temporal relation between pathological reflux and symptoms during 24-hr pH monitoring.
Pathological reflux is defined as upright acid exposure >8.4%, supine acid exposure >3.4 % and /or total acid exposure >5.8% on 24-hr pH monitoring. A documented relation between reflux and symptoms is reflected by a Symptom Association Probability (SAP) >95%.
3. Patients without a diaphragmatic hernia or a sliding hernia not exceeding 2 cm (endoscopically measured distance from Z-line and impression of the diaphragm).
4. Age between 18 and 65 years.
5. Informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Patients with a diaphragmatic hernia other than of the sliding type and/or larger than 2 cm.
2. Grade C and D esophagitis according to the Los Angeles classification.
3. Histologically proven long-segment Barrett's oesophagus.
4. Patients with severe esophageal or gastric motility disorders.
5. Patients with a history of esophageal- or gastric surgery.
6. American Society of Anaesthesiologists classification III and IV patients.
7. Patients with a psychiatric disease or other conditions making them incapable of filling out the questionnaires or completing the objective esophageal function tests.
8. Pregnancy.

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Center Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Center Utrecht and seven participating hospitals (The Netherlands)

Sponsor details
P.O. Box 85500
H.P. G04.228
Utrecht
Netherlands
3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The costs of this trial are internally covered by the eight participating hospitals in the Netherlands:

Funder Name
University Medical Center Utrecht

Funder Name
Meander Medical Center Amersfoort

Funder Name
Lange Land Hospital Zoetermeer

Funder Name
Catharina Hospital Eindhoven

Funder Name
Medical Center Leeuwarden

Funder Name
Antonius-Mesos Hospital Nieuwegein-Utrecht

Funder Name
Rivierenland Hospital Tiel

Funder Name
Amphia Hospital Breda

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