

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/02/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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