A prospective Evaluation of the Torax Medical Inc. Magnetic Esophageal Sphincter for the treatment of Gastroesophageal Reflux Disease (GERD).

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This study is conducted to evaluate a novel method of augmenting a weak Lower Esophageal Sphincter (LES) with a magnetic esophgeal sphincter device.

Ethical review	-
Status	Will not start
Health condition type	Gastrointestinal haemorrhages NEC
Study type	Interventional

Summary

ID

NL-OMON29969

Source
ToetsingOnline

Brief title
A prospective evaluation of the MES for the treatment of GERD.

Condition

- Gastrointestinal haemorrhages NEC

Synonym
GERD, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Torax Medical, Inc.
Source(s) of monetary or material Support: Opdrachtgever Torax Medical financiert de

studie

Intervention

Keyword: Laparoscopy, Reflux disease, Sphincter implant

Outcome measures

Primary outcome

• Verification of the procedural methods for placing the Magnetic Esophageal Sphincter around the LES.

• Evaluate the physiological function of the implant with manometry, fluoroscopy, and endoscopy. Additional assessment and further diagnostics if deemed necessary by investigator.

• Evaluate the reduction of GERD by patient symptomology interview at all follow-up visits and 24hr pH profile at the six month follow-up visit.

Secondary outcome

Not available

Study description

Background summary

GERD is a chronic disorder associated with substantial morbidity and a major adverse impact on patient quality lof life. In industrialized nations the disease has become increasingly commonwith an estimated prevalence in the general population of approximately 7%.
The normal physiological barrier to GERD is made up of two major components: The LES and the diaphragm. A sphincter muscle provides tone to create a high pressure zone. The LES muscle works in conjunction with the diaphragm to close the junction between the esophagus and the stomach keeping acidic contents from

refluxing into the esophagus. A competent LES keeps the esophagus closed to gastric contents and opens during swallowing to allow food to pass into the stomach. An incompetent LES, however, will open from normal gastric pressures and allow acidic contents to reflux into the esophagus. An incompetent LES is the result of a weak muscle that does not have enough tone to keep the esophagus closed.
Torax Medical, Inc. has designed a device to augment the LES. The device is designed to be placed on the external esophagus in the region of the (LES). The implant is comprised of a circumferential series of magnetic beads, where the attractive force of the magnetic beads provides additional strength to close a weak LES under normal gastric pressure.

Study objective

This study is conducted to evaluate a novel method of augmenting a weak Lower Esophageal Sphincter (LES) with a magnetic esophgeal sphincter device.

Study design

This study is a prospective, non-randomized, open label, five center registry with up to fifty (50) patients receiving the Magnetic Esophageal Sphincter. Data collected during this study include, but may not be limited to, the following:
• Proton Pump Inhibitor (PPI), H2, and/or antacid use,
• 24hr pH assessment,
• LES manometry,
• Quality of Life Scores,
• Endoscopy,
• X-ray,
• Fluoroscopy (Barium Esophagram),
• Adverse Events.
Patients will be followed for twelve months to evaluate effectiveness of the treatment and any adverse events.
Till now 3 center are gonna participate in this trial with addition to 5 center.

Intervention

The participating subjects will get the following tests in the screening period:
Endoscopy
24hr pH assesment
LES manometry
Fluoroscopy (barium esophgram)

All enrolled patients will receive the magnetic Esophageal Sphincter device. This procedure will be performed in the OLVG hospital in Amsterdam.

Patienst will be followed for 12 months to evaluate effectiveness of the treatment and any adverse events.
6 months after treatment the following tests will be perforemd:
Endoscopy
LES manometry and 24hr pH assesment
Abdominal/chest x-ray

12 months after treatment a barium esophagram and an abdominal/chest x-ray will be performed.

Study burden and risks

In the screening period the patient will visit the AMC hospital 3x for the following tests:.
LES manometry and 24hr pH assesment. For this tests the patient should be off PPI treatment for 5 days and should remain fasted from midnight the day before.
Endoscopy. He should remain fasted from midnight the day before.
Barium Esophagram. Remain fasted from 4 hours.

The implant procedure will be perofrmed in the OLVG hospital. The patient should remain fasted from midnight the day before. An abdominal/chest x-ray will be performed. Expected hospitalization will be 2 days. You could find the potential risks in the ABR form section E9. The potential benefits are described in section E9a.

Patienst will be followed for 12 months to evaluate effectiveness of the treatment and any adverse events.
6 months after treatment the following tests will be perforemd:
Endoscopy
LES manometry and 24hr pH assesment
Abdominal/chest x-ray
The same preparations as described in the screening period are required.

12 months after treatment a barium esophagram and an abdominal/chest x-ray will be performed.
The same preparations as described in the screening period are required.

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

Age _>18 years, <85 years, life expectancy >3 years
Documented history of GERD symptoms such as heartburn and regurgitation
On daily PPI treatment for at least 3 months with partially response
GERD symptoms in absence of PPI theapy
Ambulatory Esophageal pH<4_>5% or pH <4 for _>3% time in supine
Patient is a surgical candidate
Patient is able to understand provide written ICF

Exclusion criteria

The procedure is an emergency procedure
Patient is currently being treated with another investigational drug mechanical support device
Prior gastric or esophageal surgery
Any endoscopic intervention
Suspected or confirmed esophageal or gastric cancer
Hiatal hernia _>3 cm
Esophageal motility less than 30 mmHg peristaltic amplitude on wet swallows and/or > 30% synchronous/repetitive waves

Esophagitis grade IV
Symptoms of dysphagia or indications of dysphagia from esophagram
Patient has scleroderma and or achalasia
Gross esophageal anatomic abnormalities
patient is pregnant or nursing or plans to become pregnant
Barret esophagus
BMI >35

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-07-2006
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Magnetic Esophageal Sphincter implant to augment a weak LES
Registration:	No

Ethics review

Not available

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	NL12406.018.06