LINX* Reflux Management System Clinical Study

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The purpose of the study is to evaluate the safety and effectiveness of the LINX device in the treatment of GERD

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON37296

Source
ToetsingOnline

Brief title
LINX* Reflux Management System Clinical Study

Condition

- Gastrointestinal conditions NEC

Synonym
GERD, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Torax medical, Inc.
Source(s) of monetary or material Support: Torax medical Inc.

Intervention

Keyword: Laparoscopy, Reflux disease, Sphincter implant

Outcome measures

Primary outcome

Primary safety endpoint:

The primary safety endpoint is the rate of occurrence for serious de-vice and procedure related adverse events. The primary safety end-point will be assessed by reporting all adverse events and by esti-mating the rate of serious device and procedure related adverse events through 12 months post implantation. Safety will also be evaluated by endoscopy to assess the mucosa and abdominal/chest X-ray evaluations to verify device location at 12 months post im-plantation.

Primary effectiveness endpoints:

Reduction in total distal esophageal acid exposure time defined by esophageal pH testing. Testing will be performed with subjects off PPIs. The subject*s baseline pH acid exposure time will serve as the control and be compared to the subject*s pH acid exposure time 12 months post implantation.

Success criteria * At least 60% of subjects will have nor-malized or improved by at least 50% in total distal acid exposure

Secondary outcome

Secondary effectiveness endpoints:

Subjects GERD-HRQL (Health Related Quality of Life) scores will be assessed off all GERD medications. The subject*s baseline GERD-HRQL score will serve as the control and be compared to the sub-ject*s GERD-HRQL 12 months post implantation.

Success criteria - At least 60% of subjects will have a 50% reduction in total

GERD-HRQL scores

Subject*s average daily dose of PPI will be evaluated. The subject*s baseline

average daily dosage will serve as the control and be com-pared to the

subject*s average daily dosage 12 months post-procedure.

Success criteria - At least 60% of subjects will reduce their average daily PPI

dosage *50%

Number of TLESR's

Study description

Background summary

GERD, which manifests mainly as heartburn, regurgitation, or both, is a chronic disorder associated with substantial morbidity and a major adverse impact on patient quality of life. In industrialized nations the disease has become increasingly common, with an estimated prevalence in the general population of approximately 7%1. 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

The purpose of the study is to evaluate the safety and effectiveness of the

LINX device in the treatment of GERD

Study design

The study is a prospective, multi-center, single arm clinical study that will be conducted in the United States and Europe.
Approximately 2 years (includes time for enrollment and completion of 60 month follow-up).
This clinical evaluation will be conducted at up to fifteen (15) investigational centers. Investigators will be selected among surgeons with experience performing anti-reflux laparoscopic procedures.

Intervention

At screening and at 12 months post procedure:

Esophageal manometry + pH -impedance test
pH test by Bravo capsule
Endoscopy
Barium swallow
chest x-ray

At 24 and 60 months Endoscopy and chest/abdominal x-ray

Study burden and risks

Risks of LINX device implantation procedure and/or device:
* Achalasia
* Bleeding
* Death
* Device erosion
* Device explant/re-operation
* Device failure
* Device migration (device does not appear to be at implant site)
* Dysphagia
* Inability to belch or vomit
* Infection
* Impaired gastric motility
* Injury to the esophagus, spleen, or stomach
* Organ damage caused by device migration
* Pain
* Peritonitis
* Pneumothorax
* Regurgitation
* Stomach Bloating
* Worsening of preoperative symptoms (including but not lim-ited to dysphagia

or heartburn

14.1 Potential Risks
Complications associated with surgical procedures and device implants have been compiled from the scientific literature and were identified as anticipated adverse events. As with any investigational or approved device, a potential exists for the occurrence of unanticipated ad-verse events. Torax Medical has no evidence to suggest that the risk of complications asso-ciated with use of the LINX device is greater than the risks posed by other existing mar-keted products/procedures except for those potential risks which are unique to the LINX* device.

Risk
Device migration - up or down esophagus
Device integrity compromised (link breaks)
Device integrity compromised (hermetic seal failed)
Magnetic field in-teraction with elec-trical implant or metallic, abdominal implants
Toxic Response
Exposure to MRI

Potential Benefits
The potential benefit to subjects being implanted with the LINX device are: to restore the normal function of the LES; to reduce or eliminate GERD related symptoms; and to reduce or eliminate dependence on GERD medications.

Contacts

Public
Torax medical, Inc.

4188 Lexington Ave. North
MN 55126, Shoreview
US
Scientific
Torax medical, Inc.

4188 Lexington Ave. North
MN 55126, Shoreview
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age * 19 years - * 75 years
Suitable surgical candidate
Patient requires daily PPI or other anti-reflux therapy
Total distal Ambulatory Esophageal pH must be * 4.5% of the time * pH4
GERD symptoms in absence of anti-reflux therapy
Subject has signed an ICF

Exclusion criteria

The procedure is an emergency procedure
Patient is currently being treated with another investigational drug or investigational device
Prior gastric esophageal surgery
Any previous endoscopic anti-reflux intervention for GERD and /or previous endoscopic intervention for treatment of Barret's esophagus
Suspected or confirmed esophageal or gastric cancer
Hiatal hernia > 3 cm
Esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or < 70% (propulsive) peristaltic sequences
Esophagitis grade C-D
Symptoms of dysphagia more than once a week within the last 3 months
Patient diagnosed with scleroderma or achalasia, Nutcracker esophagus
Gross esophageal anatomic abnormalities or esophgeal stricture
Patient is pregnant or nursing or plans to become pregnant
Patient has Barret esophagus
BMI>35
Allergies to titanium, stainless steel, nickel or ferrous materials
Diagnosed psychiatric disorders

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	An implantable single-use LINX device intended to augment the competence of the Lower Esophageal Sph
Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL24838.018.08