ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: CS004 endostim

Previous Study | Return to List | Next Study

Feasibility Study for Evaluating the Effect of Electrical Stimulation on Lower Esophageal Sphincter Pressure and Esophageal Acid Exposure in Patients With Gastroesophageal Reflux Disease

This study has been completed.

Sponsor:
EndoStim Inc.

Information provided by (Responsible Party):
EndoStim Inc.

ClinicalTrials.gov Identifier:
NCT01578642

First received: April 11, 2012
Last updated: February 11, 2014
Last verified: January 2013
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

The **EndoStim** Stimulation System is an investigational device intended to improve the lower esophageal sphincter (LES) resting tone and restore LES function in individuals suffering with gastroesophageal reflux disease (GERD).

Condition	Intervention	Phase
Gastroesophageal Reflux Disease	Device: **EndoStim** LES Stimulation System	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Feasibility Study: An Evaluation of the Effect of Long-Term Electrical Stimulation on Lower Esophageal Sphincter (LES) Pressure and Esophageal Acid Exposure in Patients With Gastroesophageal Reflux Disease (GERD)

Resource links provided by NLM:

MedlinePlus related topics: GERD

U.S. FDA Resources

Further study details as provided by EndoStim Inc.:

Primary Outcome Measures:

- Primary Safety Endpoint [Time Frame: 3 months] [Designated as safety issue: Yes]

  Safety will be assessed by incidence and severity of adverse events through 12-week (3 month) follow-up. Included in this assessment will be the proportion of subjects with any of the following outcomes between device implant and completion of the Week 12 evaluation: (1) death, or (2) medical morbidity, including myocardial infarction, pneumonia, wound infection, or perforation requiring hospitalization.

- Primary Endpoint: Functionality [Time Frame: Up to 3 months] [Designated as safety issue: No]

  Functionality of the EndoStim system will be assessed by the ability of the device to initiate stimulation as programmed and to accurately detect the patient's posture. Indication of device detection when the patient is lying horizontally and when standing up will be recorded.

Secondary Outcome Measures:

- GERD-HRQL [Time Frame: 3 months] [Designated as safety issue: No]

Improvement in GERD-HRQL with LES stimulation at the 12-weeks (3 months) follow-up compared to baseline

- GERD Symptoms [Time Frame: 3 months] [Designated as safety issue: No]

  Changes in GERD symptoms as measured by the patient daily symptom-diary as well as the impact of GERD symptoms on quality of life as measured by SF-12 will be compared between baseline assessments and post-implant measures at 12 weeks (3 months).

- Lower Esophageal Measures [Time Frame: 3 months] [Designated as safety issue: No]

  The baseline LES end expiratory pressure and the on-stimulation LES end expiratory pressure at 3 months

- Esophageal Acid Exposure [Time Frame: 3 months] [Designated as safety issue: No]

  Total fractional esophageal acid exposure time with pH < 4.0. The data on baseline esophageal acid exposure off-therapy, prior to surgical implant of the stimulator and on-stimulation at 12 weeks (3 months) post-implant

Enrollment:	24
Study Start Date:	September 2010
Study Completion Date:	May 2013
Primary Completion Date:	May 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Single Arm open label **EndoStim** LES Stimulation System	Device: **EndoStim** LES Stimulation System The **EndoStim** LES Stimulation System comprises three components: an electrical stimulation lead an implantable pulse generator (IPG) and an external programmer.

Detailed Description:

EndoStim is developing an investigational medical device specifically designed to deliver electrical stimulation to the LES and has completed two clinical feasibility studies using the EndoStim stimulation system in fifteen subjects.

Acute electrical stimulation resulted in significant LES pressure with no adverse effects reported.

Results of these studies are promising and warrant additional clinical study to evaluate the effectiveness of EndoStim stimulation system to treat GERD over time.

In this study, EndoStim proposes using a fully implantable system. Results of this study are expected to provide confirmation of safety of long-term LES stimulation and may provide long term clinical benefit for GERD patients.

Eligibility

Ages Eligible for Study:	21 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Subject is between 21 - 65 years of age.
- Subject has a history of heartburn, regurgitation or both for > 6 months prompting physician recommendation of continual daily use of PPI before study entry.
- Baseline GERD-HRQL heartburn score of ≥ 20 off PPI assessed during the run-in phase.
- Subject has an American Society of Anesthesiologists (ASA) Physical Status Classification I or II (or comparable local classification if any).
- Subject has demonstrated satisfactory symptomatic response to a previous course of GERD therapy (≥ 2 weeks); GERD HRQL heartburn score improvement of ≥ 10 on therapy as assessed during the run in phase.
- Subject has exhibited excessive lower esophageal acid exposure during 24-hour pH-metry off antisecretory therapy performed within 6 months of enrollment; pH < 4 for > 5% of total or > 3% of supine time.
- Subject has a resting LES end expiratory pressure > 5mm Hg and < 15 mm Hg on a high resolution manometry within 6 months of enrollment.
- Subject has esophagitis ≤ Grade C (LA classification) on upper endoscopy within 6 months of enrollment.
- Subject has esophageal body contraction amplitude > 30 mmHg for > 70% of swallows and > 50% peristaltic contractions on high resolution manometry.
- Subject has signed the informed consent form.

Exclusion Criteria:

- Subject has non-GERD esophageal motility disorders.

- Subject has gastroparesis.
- Subject has significant multisystem diseases.
- Subject has scleroderma requiring therapy in the preceding 2 years .
- Subject has dermatomyositis requiring therapy in the preceding 2 years.
- Subject has Calcinosis-Raynaud's-esophaguschlerodactyly syndrome requiring therapy in the preceding 2 years.
- Subject has Sjogren's Syndrome requiring therapy in the preceding 2 years.
- Subject has Sharp's Syndrome requiring therapy in the preceding 2 years.
- Subject has persistent esophagitis greater than LA grade C.
- Subject has Barrett's epithelium (> M2; >C1) or any dysplasia.
- Subject has a hiatus hernia larger than 3 cm.
- Subject has a body mass Index greater than 35 kg/m2 .
- Subject has Type 1 diabetes mellitus
- Subject has uncontrolled Type 2 diabetes mellitus (T2DM) defined as HbA1c >9.5 in the previous 6 months, or has T2DM for > 10 years.
- Subject has an autoimmune disorder requiring therapy in the preceding 2 years.
- Subject has suspected or confirmed esophageal or gastric cancer.
- Subject has esophageal or gastric varices.
- Subject has significant cardiac arrhythmia or ectopy or significant cardiovascular disease.
- Subject has an existing implanted electrical stimulator (e.g., pacemaker).
- Subject requires chronic anticoagulant therapy.
- Subject has dysphagia or esophageal peptic structure, excluding Schatzki's ring.
- Subject is pregnant or intends to become pregnant during the trial period.
- Subject is currently enrolled in other potentially confounding research.
- Subject has any condition that, at the discretion of the investigator, would preclude participation in the trial.
- History of any malignancy in the last 2 years
- History of previous esophageal or gastric surgery, including nissen fundoplication

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01578642

Locations

Chile

INDISA Clínica da Familia
Santiago, Chile

Sponsors and Collaborators

EndoStim Inc.

Investigators

Principal Investigator: Leonardo RODRIGUEZ, M.D INDISA Clínica da Familia, Santiago, Chile

More Information

No publications provided by EndoStim Inc.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Rodríguez L, Rodriguez P, Gómez B, Ayala JC, Oxenberg D, Perez-Castilla A, Netto MG, Soffer E, Boscardin WJ, Crowell MD. Two-year results of intermittent electrical stimulation of the lower esophageal sphincter treatment of gastroesophageal reflux disease. Surgery. 2015 Mar;157(3):556-67. doi: 10.1016/j.surg.2014.10.012. Epub 2014 Nov 6.

Responsible Party: EndoStim Inc.
ClinicalTrials.gov Identifier: NCT01578642 History of Changes

Other Study ID Numbers: **CS004**
Study First Received: April 11, 2012
Last Updated: February 11, 2014
Health Authority: Chile: Institutional Review Board

Keywords provided by EndoStim Inc.:
GERD
LES Pressure
Electrical Stimulation

Additional relevant MeSH terms:

Gastroesophageal Reflux	Esophageal Diseases
Deglutition Disorders	Esophageal Motility Disorders
Digestive System Diseases	Gastrointestinal Diseases

ClinicalTrials.gov processed this record on October 01, 2015