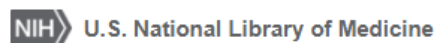


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Laparoscopy Heller Myotomy With Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM)



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02138643

Recruitment Status ⓘ : Unknown

[Verified April 2017](#) by University of Sao Paulo General Hospital.

Recruitment status was: Active, not recruiting

First Posted ⓘ : May 14, 2014

Last Update Posted ⓘ : April 12, 2017

Sponsor:

University of Sao Paulo General Hospital

Information provided by (Responsible Party):

University of Sao Paulo General Hospital

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Study Description




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Brief Summary:

Achalasia is a disorder benign esophageal motor, which is characterized by failure to relax the lower esophageal sphincter (LES) in response to swallowing associated with lack of peristalsis of the esophageal body. Its most common clinical presentation is dysphagia , and occasionally chest pain , regurgitation , aspiration pneumonia and weight loss , resulting in a large impact on daily activities and quality of life of affected individuals .

There is currently considered curative treatment for achalasia , dysphagia relief being the primary therapeutic target and is forced to relax the LES by endoscopy or surgery. Thus , the most commonly used endoscopic treatments are forced dilatation of the cardia and botulinum toxin. Laparoscopic Heller myotomy with antireflux procedure with therapy is considered "gold standard " because of excellent results and minimal invasiveness. Currently , pneumatic dilation and surgical treatment with the Heller myotomy with fundoplication are strongly associated with the best therapeutic options available .

In recent years, the possibility of using endoluminal access in the treatment of achalasia patients through the technique originally described as Natural orifices Transluminal Endoscopic Surgery (NOTES) and continuing advances in the submucosal dissection has enabled the concomitant development of a new approach described as perioral endoscopic myotomy . In 2007, Pasricha et al , described the feasibility of endoscopic esophageal myotomy through a submucosal tunnel initially in an animal model . The first performance of this procedure in humans was described by Inoue et al , in 2010 , introducing the concept of transluminal endoscopic surgery through natural orifices , with the objective of minimizing the trauma and all the stress resulting from open surgical procedure . These authors call the procedure as POEM (Per Oral Endoscopic myotomy)

Condition or disease 	Intervention/treatment 	Phase 
Dysphagia	Procedure: Endoscopic surgery	Not Applicable
Achalasia	Procedure: Laparoscopic surgery	

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Study Design

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[Study Type](#) ⓘ : Interventional (Clinical Trial)

Estimated [Enrollment](#) ⓘ : 30 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Laparoscopy Heller Myotomy With Fundoplication
Associated Versus Peroral Endoscopic Myotomy (POEM)

[Actual Study Start Date](#) ⓘ : February 2016

Estimated [Primary Completion Date](#) ⓘ : November 2017

Estimated [Study Completion Date](#) ⓘ : December 2017

Resource links provided by the National Library of Medicine



[MedlinePlus](#) related topics: [Endoscopy](#)
[Swallowing Disorders](#)

[Genetic and Rare Diseases Information Center](#) resources:
[Idiopathic Achalasia](#) [Cardiospasm](#)

[U.S. FDA Resources](#)

Arms and Interventions

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Arm ⓘ	Intervention/treatment ⓘ
Active Comparator: Endoscopic surgery Patients with symptomatic achalasia confirmed by clinical and laboratory tests, which meet the criteria for inclusion and exclusion. These will be treated with Endoscopic surgery - Peroral endoscopic myotomy (POEM)	Procedure: Endoscopic surgery These will be treated with Endoscopic surgery - Peroral endoscopic myotomy (POEM)
Sham Comparator: Laparoscopic surgery	Procedure: Laparoscopic surgery

Patients with symptomatic achalasia confirmed by clinical and laboratory tests, which meet the criteria for inclusion and exclusion. These will be treated with Laparoscopic surgery - Laparoscopic Heller myotomy.

These will be treated with Laparoscopic surgery - Laparoscopic Heller myotomy.

Outcome Measures

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Primary Outcome Measures :

1. Remission of symptoms dysphagia. [Time Frame: 12 months after the procedure performed.]

Patient selection will last for six months after the beginning of the study. Six months later, conduct additional examinations and randomization. Twelve months after the start of the project will be the completion of endoscopic surgery or laparoscopic surgery for resolution of dysphagia. The measure is a composite.

Secondary Outcome Measures :

1. Running time of the procedure and hospitalization. [Time Frame: Starts 12 months after procedure performed.]

New outpatient medical visits for clinical reassessment, more precisely 30 days, 3 months, 6 months and 12 months after the procedure will be scheduled to measure the execution time of the procedure and hospitalization. The measure is a composite.

Eligibility Criteria

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Information from the National Library of Medicine



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, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patients between 18 and 70 years diagnosed with symptomatic achalasia (dysphagia score \geq II and Eckardt $>$ 3) all grades including Rezende classification and Chicago Classification.
- Patients who agree to participate in the study and signed an informed consent.

Exclusion Criteria:

- Treatment (s) prior (s) achalasia.
- Patients with a history of esophageal, mediastinal and / or gastric surgery (except for gastric perforation).
- Patients with liver cirrhosis and / or esophageal varices, Barrett's esophagus, esophageal stricture, premalignant or malignant esophageal lesions and coagulopathy.
- Patients with severe cardiopulmonary disease or other serious illness that results in a high surgical risk.
- Patients diagnosed with pseudoachalasia
- Patients diagnosed with diverticulum in the distal esophagus.
- Pregnancy and lactation.

Contacts and Locations

Go to 

Information from the National Library of Medicine



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Please refer to this study by its ClinicalTrials.gov identifier (NCT number):

NCT02138643**Locations****Brazil**

Hospital das Clínicas da FMUSP
São Paulo, SP, Brazil, 05403000

Sponsors and Collaborators

University of Sao Paulo General Hospital

Investigators

Principal Investigator: Paulo Sakai Hospital das Clínicas da FMUSP
Study Director: Eduardo Turiani H de Moura Hospital das Clínicas FMUSP

More InformationGo to 

Responsible Party: University of Sao Paulo General Hospital
ClinicalTrials.gov Identifier: [NCT02138643](#) [History of Changes](#)
Other Study ID Numbers: 23460613000000068
First Posted: May 14, 2014 [Key Record Dates](#)
Last Update Posted: April 12, 2017
Last Verified: April 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Keywords provided by University of Sao Paulo General Hospital:

Achalasia
Megaesophagus
Peroral endoscopic myotomy(POEM)
Laparoscopic Heller myotomy

Additional relevant MeSH terms:

Esophageal Achalasia Gastrointestinal Diseases
Deglutition Disorders Digestive System Diseases

Esophageal Diseases

Esophageal Motility Disorders