

Per-oral endoscopic submucosal myotomy (POEM) for treatment of achalasia: International multi-center trial

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Primary Objective: • To evaluate treatment success, defined as successful symptom relief based on an Eckhard score

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON35807

Source

ToetsingOnline

Brief title

POEM

Condition

- Gastrointestinal stenosis and obstruction

Synonym

achalasia, benign esophageal stenosis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endoscopic, myotomy, submucosal

Outcome measures

Primary outcome

Treatment success defined as successful symptom relief based on an Eckhard score ≤ 3 at 3 months, 12 months and 5 years.

Secondary outcome

- Safety standards, defined as a rate of serious adverse events $< 2\%$. SAE are defined as death, mediastinitis, peritonitis, any complication requiring emergency/salvage surgery. The ethics committee Hamburg will function as safety monitoring board and will receive a report after each 10 patients have completed the 3 month follow-up.
- Other Adverse events
- Lower esophageal sphincter (LES) pressure (manometry) pre- and post ESMO.
- Reflux scores before, and 3 and 6 months, and 1, 2, 3, and 5 years aft post procedure.
- Functional changes pre- and post therapy of the gastro-esophageal junction as measured by the functional endoscopic probe (Endoflip)

Study description

Background summary

Achalasia is a rare neurodegenerative esophageal motility disorder, which is characterized by incomplete lower esophageal sphincter (LES) relaxation, increased LES tone, and aperistalsis of the esophagus. Clinical symptoms include dysphagia, regurgitation, and chest pain. Available treatment

strategies are either endoscopic or surgical. Endoscopic therapies consist of either balloon dilatation (EBD) or botulinum toxin injection. The surgical treatment for achalasia is Heller Myotomy with or without fundoplication, which can be performed either open or by laparoscopy. Surgical therapy has superior long-term efficacy compared to EBD and EBTI, with sustained therapeutic effects in approximately 90% of patients. The concept of Natural Orifice Transluminal Endoscopic Surgery (NOTES) has inspired endoscopists to modify existing surgical techniques towards purely endoscopic approaches. This has led to the development of Endoluminal submucosal myotomy (POEM) for the treatment of achalasia.

Study objective

Primary Objective:

- To evaluate treatment success, defined as successful symptom relief based on an Eckhard score ≤ 3 .

Secondary Objectives:

- Safety standards, defined as a rate of serious adverse events $< 2\%$. SAE are defined as death, mediastinitis, peritonitis, any complication requiring emergency/salvage surgery.
- Other adverse events
- Lower esophageal sphincter (LES) pressure (manometry) pre- and post POEM.
- Reflux scores before, and 3 and 6 months, and 1, 2, 3, and 5 years aft post procedure.
- Functional changes pre- and post therapy of the gastro-esophageal junction as measured by the functional endoscopic probe (Endoflip).

Study design

Prospective, single arm, European multi centre trial

Intervention

POEM procedures will be conducted as described by Inoue et al. A forward-viewing upper endoscope (GIF 180J) is used with a transparent distal cap attachment. Carbon dioxide gas is necessary for insufflation during the procedures. An ESD knife is used to access the submucosa, dissect the submucosal tunnel and also to divide circular muscle bundles over a length of approximately 10cm, extending a minimum of 2cm onto the cardia. A electrogenerator is used with spray coagulation mode (effect 2, 50 watt). A coagulating forceps is used for hemostasis as needed. Closure of the mucosal entry site is performed using standard endoscopic clips. The procedure steps are illustrated in Figure 1.

Study burden and risks

For this study patients will be treated with a new complete endoscopic technique for the treatment of achalasia. Feasibility and long-term effectiveness will be scored. Risks associated with the POEM procedure include a bleeding during or after treatment and a perforation of the oesophagus or stomach during the treatment procedure. These severe complications need to be treated immediately; this may imply additional endoscopic or surgical procedures with extension of admission time. To determine long term effectiveness patients are followed for a period of five years and need to undergo different esophageal examinations, additionally, they need to fill out questionnaires regularly. The procedure does not require abdominal incisions. Compared to surgical treatment of achalasia this can be a possible benefit as abdominal incisions are associated with pain, infection and longer admission time.

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

- Patient with symptomatic achalasia and pre-op barium swallow manometry and esophago-gastro-duodenoscopy which are consistent with the diagnosis
- Persons of age > 18 years with medical indication for surgical myotomy or endoscopic balloon dilatation
- Signed written informed consent.

Exclusion criteria

- Patients with previous surgery of the stomach or esophagus
- Patients with known coagulopathy
- Previous achalasia-treatment with surgery
- Patients with liver cirrhosis and/or esophageal varices
- Active esophagitis
- Eosinophilic esophagitis
- Barrett's esophagus
- Pregnancy
- Stricture of the esophagus
- Malignant or premalignant esophageal lesion

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated): 01-08-2011

Enrollment: 10

Type: Actual

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	NL36497.018.11