

Endoscopic versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON47726

Source

ToetsingOnline

Brief title

ELMA Trial (Endoscopic versus Laparoscopic Myotomy in Achalasia)

Condition

- Gastrointestinal motility and defaecation conditions

Synonym

Achalasia, Oesophageal Motility disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universitätsklinikum Hamburg-Eppendorf

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

Intervention

Keyword: Achalasia, Heller myotomy, POEM, Treatment

Outcome measures

Primary outcome

Treatment success defined as an Eckardt score of 3 or less at two years after treatment. The primary endpoint is measured after two years, but follow-up is continued up to 5 years.

Secondary outcome

- Manometry data 3 month after treatment.
- Reflux scores (clinical DeMeester score) 3 and 6 months, 1, 2, 3 and 5 years post-treatment.
- pH-impedance data at 3 month after treatment.
- Adverse events.
- Quality of life assessment (gastrointestinal LQ index by Eypasch, Wood-Dauphinee and Troidl) 3 months, 2 and 5 years after treatment.
- EGD findings at 3 months and - optional * at 2 and 5 years after treatment.

Study description

Background summary

Idiopathic achalasia is a rare motility disorder of the oesophagus that is characterised by aperistalsis of the oesophageal body and dysrelaxation of the lower oesophageal sphincter caused by progressive destruction and degeneration of the neurons in the myenteric plexus. This leads to subsequent retention of food and saliva in the oesophagus, resulting in the typical symptoms of achalasia such as dysphagia, chest pain, regurgitation of undigested food and weight loss. The cause of the neuronal degeneration found in achalasia is unknown.

Treatment of achalasia is focused on symptom relief, which is obtained by destroying the occluding function of the spastic lower oesophageal sphincter. Endoscopic therapies consist of either balloon dilatation or botulinum toxin injection. Endoscopic botulinum toxin injections can induce an effective reduction of the pressure in the lower oesophageal sphincter and thereby reduced symptoms. However the treatment is reversible and as a consequence has a high recurrence rate. Usually, endoscopic balloon dilatation is the first step in the treatment of achalasia. The success rate varies widely between 60-85% and symptom recurrence continues to occur with time which requires subsequent treatment sessions. Also, approximately 3% of the endoscopic balloon dilatation is complicated by a perforation, which is potentially a life-threatening situation. The surgical treatment for achalasia is Heller Myotomy, nowadays almost exclusively performed laparoscopically. During a surgical myotomy the circular muscle fibers of the lower oesophageal sphincter and the distal oesophagus are cut. A recent meta-analysis of 105 studies reporting on 7855 patients demonstrated that laparoscopic Heller myotomy is the most effective therapy for achalasia, especially on the long-term. However, this technique can also be associated with severe complications, is more invasive than endoscopic treatment and is more expensive as it involves laparoscopic instrumentarium and an operation theatre.

Recently, per-oral endoscopic myotomy (POEM) has been introduced as an alternative to surgical myotomy. The POEM technique is entirely endoscopic. Using an endoscopic knife, an entry to the submucosal space is made in the oesophagus and after creating a submucosal tunnel towards the lower oesophageal sphincter the circular muscle layers are cut. At the end of the procedure the mucosal opening is closed with clips. Single center studies demonstrate promising short-term results of POEM for the treatment of achalasia. At present, POEM has the potential to be the first scarless flexible endosurgical intervention to become an established clinical treatment. For this to happen, however, comparative data with established treatments such as surgical myotomy regarding safety and efficacy are necessary.

Study objective

We hypothesize that the long-term efficacy of POEM is comparable to the efficacy of laparoscopic Heller myotomy in treatment of patients with symptomatic idiopathic achalasia. The assumption is thus that POEM is non-inferior to laparoscopic Heller myotomy with respect to efficacy and safety. Therefore the objective of the study is to compare safety and long-term efficacy of POEM to laparoscopic Heller myotomy, the current gold-standard.

Study design

International multicentre randomised clinical trial.

Intervention

Study subjects undergo a Laparoscopic Heller Myotomy or a POEM.

Laparoscopic Heller Myotomy (LHM): The LHM is a laparoscopic procedure performed by a surgeon. A five trocar technique is used, a midline or left paramedian trocar is used for the camera: two lateral trocars for elevating the liver and retraction of the stomach and two trocars for dissection and suturing. The myotomy is performed by dividing both muscle layers, extending upwards into the thoracic cavity at least 4 cm above the gastro-oesophageal junction and at least 3 cm inferiorly over the stomach. An anterior fundoplication according to Dor is routinely performed. The fundus is sutured to the right lateral edge of the myotomy.

Per-oral Endoscopic Myotomy (POEM): The POEM technique is entirely endoscopic. Using an endoscopic knife, an entry to the submucosal space is made in the oesophagus and after creating a submucosal tunnel towards the lower oesophageal sphincter the circular muscle layers are cut. At the end of the procedure the mucosal opening is closed with clips.

Study burden and risks

Study subjects with symptomatic idiopathic achalasia will undergo a POEM or LHM. LHM is a safe and regularly performed procedure for patients with achalasia and will be performed by an experienced surgeon (* 30 laparoscopic gastro-esophageal junction operations of which 5 myotomies). POEM is a relative new procedure in the treatment of achalasia and will be performed by experienced endoscopists that have performed over 10 POEM procedures. For both treatments complications such as a perforation and bleeding can occur. In most cases these complications can be treated directly during the procedure but in some cases it is possible that an additional endoscopic or surgical procedure is needed with extension of admission time.

To determine long term effectiveness patients are followed for a period of five years and need to undergo different oesophageal examinations like a gastroscopy, a timed barium oesophagography, high resolution manometry and a 24 hour pH-impedance monitoring. These measurements are routinely performed in all treated achalasia patients to monitor recurrence of symptoms. All the additional measurements are safe procedures with minimal complications and routinely performed in the clinical setting. Furthermore the study subjects need to fill out questionnaires. After the initial procedure study subjects need to visit the outpatient clinic five times for follow-up.

The first results of the POEM are very promising and suggest that this treatment is comparable to LHM or even better. The risk of both procedures are the same. Patients that are not participating in this trial will in any case

undergo a treatment because of persisting symptoms. The study will give insight in the optimal treatment for symptomatic idiopathic achalasia which will have consequences for the choice of the treatment for this disease.

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

* Patients with symptomatic achalasia with:

- an Eckardt score of >3 .

- pre-operative barium swallow, manometry and esophago-gastro-duodenoscopy which are

consistent with the diagnosis.

* Patients are classified as achalasia type I-III according to the Chicago classification.

- * Age > 18 years.
- * Signed written informed consent.

Exclusion criteria

- * Patients with previous surgery of the stomach or oesophagus.
- * Patients with known coagulopathy.
- * Previous surgical achalasia treatment (like POEM or Heller myotomy).
- * Patients with liver cirrhosis and/or oesophageal varices.
- * Eosinophilic oesophagitis.
- * Barrett's oesophagus.
- * Pregnancy.
- * Stricture of the oesophagus.
- * Malignant or premalignant oesophageal lesion
- * Severe candida oesophagitis.
- * Hiatal hernia > 1cm.
- * Extensive, tortuous dilatation (>7cm luminal diameter, S shape) of the oesophagus.
- * Advanced malignant tumor with prognosis < 2 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO	
Date:	20-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-07-2019
Application type:	Amendment
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
ClinicalTrials.gov	NCT01601678
CCMO	NL43954.018.13