Pneumodilation Or Endoscopic Myotomy in Achalasia trial

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To compare the efficacy of POEM to the efficacy of endoscopic pneumodilatation as the initial treatment of symptomatic idiopathic achalasia. The treatment succes is defined as symptom relief based on a Eckhardt score of 3 or less at 3 months, 1 year...

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

Summary

ID

NL-OMON39025

Source
ToetsingOnline

Brief title
POEMA

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Achalasia, Oesophageal motility disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Achalasia, Endoscopic, Myotomy, Pneumodilation

Outcome measures

Primary outcome

Primary endpoint is treatment success, defined as an Eckardt score of 3 or less in the absence of the need for endoscopic or surgical retreatment and the absence of severe complications associated with treatment. The primary endpoint is measured after two years, but follow up is continued up to 5 years.

Secondary outcome

- Quality of life and achalasia-specific quality of life

- Stasis in the oesophagus, measured with a timed barium oesophagogram

- Presence of reflux symptoms, reflux oesophagitis and excessive oesophageal acid exposure

- Lower oesophageal sphincter pressure and integrative relaxation pressure (IRP4), as measured with high-resolution manometry

- Complications of the treatment, defined as any unwanted events that arise following treatment and/or that are secondary to the treatment. Complications are classified as *severe* when these result in admission > 24 hours or prolongation of an already planned admission of >24 hours, admission to a medium or intensive care unit, additional endoscopic procedures, or blood transfusion or death. Other complications are classified as *mild*.

- The need for endoscopic or surgical retreatment after the initial treatment session

Study description

Background summary

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 achalasiais is unknown.
Treatment of achalasia is focused on symptom relief, which is obtained by destroying the occluding function of the spastic lower oesophageal sphincter. Treatment options are endoscopic dilatation by a pneumatic balloon, the golden standard, or Heller myotomie a surgical treatment performed by laparoscopy. Endoscopic pneumodilatation can be complicated by a perforation and there is a relative high chance of symptom recurrence which requires subsequent treatment sessions. The surgical treatment can also be associated with severe complications, like a perforation, and is more invasive. Currently endoscopic pneumodilatation is the first choice of treatment in patients with achalasia and surgical myotomy is generally performed in case of symptom recurrence after initial pneumodilatation. The recent developments on minimal invasive surgical techniques has led to the development of per-oral endoscopic submucosal myotomy (POEM) for the treatment of achalasia. The first results of the POEM are very pe and suggest that this treatment is better than the endoscopic pneumodilation, the golden standard.

Study objective

To compare the efficacy of POEM to the efficacy of endoscopic pneumodilatation as the initial treatment of symptomatic idiopathic achalasia. The treatment succes is defined as symptom relief based on a Eckhardt score of 3 or less at 3 months, 1 year and 5 year after treatment. Furthermore there is an absence of severe complications associated with the treatment and there is no need for endoscopic or surgical retreatment between the first treatment en the primary endpoint at two years after treatment.

Study design

Multicentre randomised clinical trial.

Intervention

Study subjects undergo a POEM or endoscopic pneumodilatation

Per-oral endoscopic submucosal myotomy (POEM): The POEM tehcnique 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.

Endoscopic pneumodilatation: Endoscopic dilatation of the lower oesophageal sphincter is performed by a Rigiflex balloon of 30mm and in case a second dilatation is necessary a Rigiflex balloon of 35mm is used. A second dilatation is performed if the Eckhardt symptomscore is above 3, three weeks after the first dilatation or if at the the high resolution manometry the integrative relaxation pressure (IRP4) is above the 10mmHg. A second dilatation within 6 weeks is not considered a failure but considered as a part of the regular treatment.

Study burden and risks

For this study patients will be treated with a per-oral endoscopic submucosal myotomy (POEM) or endoscopic pneumodilatation for the treatment of achalasia. Both procedures are associated with risks, including a bleeding during or after treatment, a perforation of the oesopahgus or stomach during the treatment and an infection after treatment. These complications could be severe and need in some cases immediately treatment. 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 oesophageal examinations like a gastroscopy, a timed barium oesophagogram, high resolution manometry and a 24 hour pH-impedance monitoring. Furthermore they need to fill out questionnaires regularly. After 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 better than the endoscopic pneumodilation, the golden standard. The risks of both procedures are the same. Furthermore patients that are not participating in the trial will undergo a treatment anyway, in most cases this will be endoscopic pneumodilatation.

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

- Presence of achalasia, as shown on oesophageal manometry
- Eckardt score > 3
- Age between 18-80 years
- Signed written informed consent
- ASA class I or II

Exclusion criteria

- Previous endoscopic or surgical treatment for achalasia, except botulinium toxin injections
- Previous surgery of the stomach or oesophagus
- Patients with known coagulopathy
- Presence of liver cirrhosis and/or oesophageal varices
- Presence of eosinophilic oesophagitis
- Presence of Barrett*s oesophagus
- Pregnancy at time of treatment
- Presence of a stricture of the oesophagus
- Presence of malignant or premalignant oesophageal lesions

- Presence of an extensive, tortuous dilated oesophageal body (S-shape)
- Presence of a diverticula in the distal oesophagus

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):	21-09-2012
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Not approved Date:	12-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2014
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
CCMO	NL40053.018.12