Pneumodilation versus Per-Oral Endoscopic Myotomy in Achalasia patients with recurrent symptoms after Laparoscopic Heller Myotomy trial

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To compare the efficacy of POEM to the efficacy of pneumodilation for the treatment of recurrent symptoms in patients with idiopathic achalasia that previously underwent Heller myotomy.

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

Summary

ID

NL-OMON50756

Source
ToetsingOnline

Brief title
POEMA 2

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Achalasia, oesophageal motiliy 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

- Treatment success at one year, defined as: An Eckardt score of 3 or less in the absence of additional retreatment after the allocated treatment (patients in the pneumodilation arm undergo 2 pneumodilations, with 30 and 35 mm and another one or two pneumodilations are allowing up to 40 mm in case of symptom recurrence within 1 year), patients in the POEM arm undergo POEM and no subsequent treatments)

Secondary outcome

- Quality of life and achalasia-specific quality of life
- Stasis in the oesophagus, measured with a timed barium oesophagogram
- 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*.
- Treatment success after two and five years follow up
- The use of acid-suppressant drugs and the presence of reflux symptoms using the GerdQ questionnaire

- The presence of reflux oesophagitis, as observed during upper endoscopy

Study description

Background summary

Achalasia is a rare motility disorder of he oesophagus that is characterised by aperistalsis of the oesophageal body and dysrelaxation of the lower oesophageal sphincer caused by progressive destruction and degenaration 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 in still unknown.

Study objective

To compare the efficacy of POEM to the efficacy of pneumodilation for the treatment of recurrent symptoms in patients with idiopathic achalasia that previously underwent Heller myotomy.

Study design

Multicenter randomised clinical trial

Intervention

Study subjects undergo a POEM or endoscopic pneumodilation

Per-oral submucosal myotomy (POEM): the POEM is entirely endoscopic. Using and endoscopic knife, an entry o he submucosal space is made in the oesophagus and after creaing a submucosal tunnel towars the lower oesophageal sphincter the cicular muscle layers are cut. At the end of he pocedure the mucoal opening is closed with clips.

Endoscopic pneumodilation: endoscopic dilation of the lower oesophageal spincer is performen by a Rigiflex balloon of 30 mm and after 1-3 weeks of 35 mm. A third dilation with a 40mm balloon is performed, if patients suffer from persistent or recurrent symptoms wihing 3 months. If symptoms return with 3-12 months, two additional dilations will be performed using a 35 and 40 mm balloon.

Study burden and risks

For this study patients will be treated with per-oral endoscopic submucosal myotomy (POEM) or endoscopic pneumodilation for the treatment of persistent or recurent symptoms of achalasie. Both procedures are associated with risks, including bleeding during or after treatment, a perforation of the oesophagus or stomach during the treatment and infection after treatment. These complications could be severe and are, in some cases, in need of immediate care. This may imply additional endoscopic of surgical procedures with extension of admission time.

To determine long term effectiveness patients are followed fo a period of 5 years and need to undergo different eosophageal examinations like a gastroscopy, a timed barium oesophagram, high resolution manometry and a 24 hour ph-impedance measuremet. Furthermore, the need to fill out questionnaires regularly. After the procedures subjecs need to visit the outpatient clinic at least 5 times or follow-up.

The first resuls of the POEM are very promising and suggest at this treatmen is beter than he endoscopic pneumodilation. The risks of both procedures are equal. Furthermore, patients that are not participating in the trial will also undergo a treament, in most cases this will be endoscopic pneumodilation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

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 at least once
Previous Heller myotomy
Eckardt score > 3
Significant stasis (stasis of >=2 cm on barium oesophagogram after two minutes)
Age between 18-80 years
Signed written informed consent

Exclusion criteria

Previous pneumodilations after the Heller myotomy (pneumodilations before the Heller myotomy are allowed)
Previous (attempt at) POEM
Previous surgery of the stomach or oesophagus, except Heller myotomy
Known coagulopathy
Presence of liver cirrhosis and/or oesophageal varices
Presence of eosinophilic oesophagitis
Pregnancy at time of treatment
Presence of a stricture of the oesophagus
Presence of malignant or premalignant oesophageal lesions
Presence of one or more large esophageal diverticuli

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:	Recruiting
Start date (anticipated):	13-04-2014
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-09-2017
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

ID: 25721
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL48223.018.14

Register	ID
OMON	NL-OMON25721