

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25721

### Source

NTR

### Brief title

POEMA-2

### Health condition

achalasia  
Per-oral endoscopic myotomy  
Relapse  
Pneumodilation  
Secondary treatment  
Laparoscopic Heller Myotomy

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC) Amsterdam

**Source(s) of monetary or material Support:** Gastroenterology department

AMC Amsterdam, C2  
Meibergdreef 9  
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The Netherlands

## Intervention

## 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

Summary POEMA-2 trial

Idiopathic achalasia is a rare motility disorder of the oesophagus with an annual incidence rate of 1

per 100,000 persons. Achalasia is 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. On the long term, incomplete oesophageal emptying and reflux

result in an increased risk for development of squamous cell carcinoma of the oesophagus. The cause

of the neuronal degeneration found in achalasia is unknown.

Treatment procedures include: endoscopic pneumodilations (PD) and laparoscopic Heller myotomy.

Unfortunately, some patients experience recurrent or persistent symptoms after pneumodilations

and Heller myotomy. Patients with recurrent symptoms after undergoing a laparoscopic Heller

myotomy are usually treated with pneumodilation . However, the success rates of pneumodilation

after laparoscopic Heller myotomy are only between 50-67% leaving a substantial proportion of these

patients with recurrent symptoms.

Recently, a new procedure has been introduced, the per-oral endoscopic myotomy. During per-oral

endoscopic myotomy the circular muscle layers of the lower oesophageal sphincter are cut similar

to the Heller myotomy, but the approach is through the wall of the esophagus with the endoscope

instead of laparoscopically.

This study compares 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.

This study is a multicenter randomized clinical trial, including adult patient with persistent or recurrent symptomatic idiopathic achalasia after Heller myotomy.

### **Study objective**

We hypothesize that per-oral endoscopic myotomy has a higher long-term efficacy than pneumodilation in treatment of patients with recurrent symptoms after Heller myotomy

### **Study design**

3 months, 1, 2 and 5 years

### **Intervention**

per-oral endoscopic myotomy (intervention)

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Presence of achalasia as shown on oesophageal manometry at least once
2. Previous Heller myotomy
3. Eckardt score > 3

4. Significant stasis (stasis of >2 cm on barium oesophagogram after two minutes)
5. Age between 18-80 years
6. Signed written informed consent

## Exclusion criteria

1. Previous pneumodilations after the Heller myotomy (pneumodilations before the Heller myotomy are allowed)
2. Previous (attempt at) POEM
3. Previous surgery of the stomach or oesophagus, except Heller myotomy
4. Known coagulopathy
5. Presence of liver cirrhosis and/or oesophageal varices
6. Presence of eosinophilic oesophagitis
7. Pregnancy at time of treatment
8. Presence of a stricture of the oesophagus
9. Presence of malignant or premalignant oesophageal lesions
10. 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

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-05-2014  
Enrollment: 45  
Type: Anticipated

## Ethics review

Not applicable  
Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 50756  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL4361
NTR-old	NTR4501
CCMO	NL48223.018.14
OMON	NL-OMON50756

## Study results