Pneumodilation Or Endoscopic Myotomy in Achalasia (POEMA) Trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21319

Source
NTR

Brief title
POEMA

Health condition

Achalasia, Pneumodilation, Per-Oral Endoscopic Myotomy (POEM)

Sponsors and support

Primary sponsor: AMC Amsterdam (University Medical Centre)
Source(s) of monetary or material Support: AMC Amsterdam

Intervention

Outcome measures

Primary outcome

The primary outcome is treatment succes, defined as:

1. An Eckardt score of 3 or less;

2. The absence of the need for endoscopic or surgical retreatment in the period between the

first treatment session (first and optional second dilation within first 3 months) and the endpoint;

3. The absence of severe complications
associated with treatment.

Secondary outcome

1. Quality of life and achalasia-specific quality of life;

2. Stasis in the oesophagus, measured with a timed barium oesophagogram;

3. Presence of reflux symptoms, reflux oesophagitis and excessive oesophageal acid exposure;

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

5. 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”;

6. 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 that control the esophageal muscles. Symptoms of achalasia are dysphagia, chest pain, regurgitation and weight loss.

Treatment of achalasia is focused on symptom relief, which is obtained by destroying the occluding function of the spastic lower oesophageal sphincter. Usually, the first choice of treatment is endoscopic dilation of the lower oesophageal sphincter using a pneumatic balloon.
Recently, per-oral endoscopic myotomy has been introduced. With this technique, the circular muscle layers of the lower oesophageal sphincter are cut endoscopically. The first results of open labels studies with endoscopic myotomy are very positive and suggest this treatment may be superior to pneumodilation.

In order to investigate this, we have designed a multicenter randomised controlled trial in which we compare pneumodilation to endoscopic myotomy. Adult patients with symptomatic achalasia that have not been treated before are included. Required sample size is calculated at 130 patients.
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. Primary endpoint is measured after two years, but follow up is continued up to 5 years. Follow up tests consist of symptom and quality of life questionnaires, upper endoscopy, barium esophagogram, esophageal high-resolution manometry and reflux monitoring using pH-impedance monitoring.

Recruiting countries: The Netherlands, USA, Hong Kong, Italy, Germany.

Study objective

The aim of the study is to compare the efficacy of per-oral endoscopic myotomy (POEM) to the efficacy of pneumodilation as the initial treatment of symptomatic idiopathic achalasia. It is hypothesized that POEM has a higher long-term efficacy than pneumodilation in treatment of therapy-naive patients with idiopathic achalasia.

Study design

1. Baseline:

A. Venous blood withdrawal;

B. Questionnaires (SF-36, achalasia-DSQoL, GerdQ and Eckardt);

C. Timed barium oesophagography;

D. High Resolution Manometry;

E. Upper endoscopy.

2. 3 weeks after treatment (only for pneumodilation):

A. Eckardt;

B. HRM dependent on Eckardt.

3. 3 months after treatment:

A. Questionnaires;

B. Timed barium oesophagography;

C. HRM.

4. 1 year after treatment:

A. Questionnaires;

B. Timed barium oesophagography;

C. HRM;

D. Upper endoscopy;

E. pH-impedance recording.

4. 2 years after treatment:

A. Questionnaires;

B. Timed barium oesophagography;

C. HRM;

D. Upper endoscopy.

5. 5 years after treatment:

A. Questionnaires;

B. Timed barium oesophagography;

C. HRM;

D. Upper endoscopy.

Intervention

Therapy-naive patients with idiopathic achalasia will undergo per-oral endoscopic myotomy (POEM) or pneumodilation, depend on the randomization. The POEM will be performed in one procedure. For the pneumodilation participants will be dilated once or twice, depending on the symptoms that will be evaluated 3 weeks after the first pneumodilation. In case the Eckardt (symptom score for achalasia) is > 3 a second pneumodilation will be performed. If the Eckardt score is < 3 an additional high resolution manometry will be performed to see if a second dilation is necassary.

Before and after the procedure the following interventions will take place for baseline data and the follow-up:

1. Venous blood withdrawal;

2. Upper Endoscopy;

3. Timed barium oesophagography;

4. High Resolution Manometry (HRM);

5. pH-impedance monitoring;

6. Questionnaires (SF-36, Achalasia-DSQoL, GerdQ and Eckardt score).

Contacts

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Eligibility criteria

Inclusion criteria

1. Presence of achalasia, as shown on oesophageal manometry;

2. Eckardt score > 3;

3. Age between 18-80 years;

4. Signed written informed consent;

5. ASA class I or II.

Exclusion criteria

1. Previous endoscopic or surgical treatment for achalasia, except botulinium toxin injections;

2. Previous surgery of the stomach or oesophagus;

3. Known coagulopathy;

4. Presence of liver cirrhosis and/or oesophageal varices;

5. Presence of eosinophilic oesophagitis;

6. Presence of Barrett’s oesophagus;

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 an extremely dilated oesophageal body (>6cm).

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):	01-10-2012
Enrollment:	130

Type:	Anticipated

Ethics review

Positive opinion Date:	29-08-2012
Application type:	First submission

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
NTR-new	NL3442
NTR-old	NTR3593
CCMO	NL-40053.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A