

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

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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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25721

Bron

NTR

Verkorte titel

POEMA-2

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam

Overige ondersteuning: Gastroenterology department

AMC Amsterdam, C2

Meibergdreef 9

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3 months, 1, 2 and 5 years

Onderzoeksproduct en/of interventie

per-oral endoscopic myotomy (intervention)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50756

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten