

# The incidence of perioperative complications during anaesthesia for Peroral Endoscopic Myotomy (POEM) in oesophageal achalasia

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26349

### Source

NTR

### Brief title

POEM

### Health condition

Oesophageal achalasia

## Sponsors and support

**Primary sponsor:** Department of Anesthesiology, Amsterdam University Medical Center, location AMC

**Source(s) of monetary or material Support:** None

## Intervention

## Outcome measures

### Primary outcome

The incidence of perioperative complications, in patients undergoing Peroral Endoscopic Myotomy (POEM), for oesophageal achalasia, in the different induction and intubation techniques.

## Secondary outcome

The number of perioperative aspirations that occur in patients undergoing Peroral Endoscopic Myotomy (POEM), for oesophageal achalasia

# Study description

## Background summary

Oesophageal achalasia is a disease which is defined as the impaired relaxation of the lower oesophageal sphincter (LES) and a lack of peristalsis in the distal oesophagus. This causes an accumulation of ingested liquids and foods in the oesophagus, which can lead to clinical symptoms including dysphagia, regurgitation and chest pain.

Oesophageal manometry is required to establish the diagnosis and a barium oesophagogram is performed when manometry gives equivocal results. The oesophagram produces the classic “bird’s beak sign”. Using a population-based approach, the incidence of treated achalasia is 1.63/100,000 with a prevalence of 10.82/100,000. The disease occurs at all ages, but more often in patients between the ages of 25 and 60 years and can be idiopathic. In some cases, associations with achalasia-like motor abnormalities can be made, including amyloidosis and neurofibromatosis type I.

Treatment of oesophageal achalasia is aimed at decreasing the LES resting pressure, to assist the passage of the accumulated liquids and foods into the stomach. There are multiple therapies for treating oesophageal achalasia, including pneumatic dilation and a laparoscopic Heller myotomy. Peroral endoscopic Myotomy (POEM) is a recently developed revolutionary therapy, which utilizes an interventional endoscopy to create a myotomy. Numerous studies have demonstrated that POEM produces comparable, if not superior results, compared to standard laparoscopic Heller myotomy. When compared to pneumatic dilation, POEM is more durable and efficient without the need for repetition.

The procedure is performed under general anaesthesia with endotracheal intubation. Due to the accumulation of oesophageal liquids and foods, patients potentially have a higher risk of complications, including aspiration. Multiple strategies are used to reduce this risk, varying from positioning techniques (supine- or seated position), induction techniques (Rapid Sequence Induction (RSI), Awake Fiberoptic Intubation (AFOI) or a normal induction), increased preoperative fasting times, preoperative endoscopic screening and possible emptying of oesophageal contents. Löser et al., concluded in a recently published review that international institutional practices vary broadly, and evidence-based recommendations regarding anaesthesia are still lacking.

Worldwide there is a lack of evidence which induction and intubation strategy should be used. This research will compare the strategies used in the Amsterdam UMC, location AMC regarding the risk of complications, including aspiration. This data may help to optimize the

anesthesiological approach used in Peroral Endoscopic Myotomy without compromising patient safety.

### **Study objective**

We aim to compare the anesthetic strategies used in the Amsterdam UMC, location AMC, and determine the incidence of complications (in particular, aspiration) with relation to the type of induction method used.

### **Study design**

Timepoints: Baseline: fasting times, T1 = incidence of aspiration and other complications immediately after anesthetic induction, T2 = incidence of aspiration and other complications at end of POEM procedure, T3 = incidence of aspiration and other complications at follow-up 3-7 days after POEM

## **Contacts**

### **Public**

Amsterdam Universiteits Medisch Centrum. locatie AMC  
Jennifer Breel

0610019257

### **Scientific**

Amsterdam Universiteits Medisch Centrum. locatie AMC  
Jennifer Breel

0610019257

## **Eligibility criteria**

### **Inclusion criteria**

- Age  $\geq 18$  years
- Patients already operated on or scheduled for Peroral Endoscopic Myotomy in Amsterdam UMC, location AMC
- Willing and able to sign consent-letter for the re-use of care data

## Exclusion criteria

- Patients who objected against the re-use of their care data
- Patients who do not sign a consent letter for the re-use of their care data

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	26-05-2021
Enrollment:	300
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	03-05-2021
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	NL9504
Other	METC AMC : W21_268 # 21.295

## Study results