Reflux symptoms in patients with achalasia.

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To investigate the underlying mechanisms of gastroesophageal reflux and gastroesophageal reflux symptoms in treated achalasia patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON37315

Source
ToetsingOnline

Brief title
Reflux symptoms in achalasia

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Achalasia, Oesophageal motility 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, Post-treatment, Reflux symptoms

Outcome measures

Primary outcome

Gastroesophageal reflux episodes.

Secondary outcome

LES pressure.

Esophagogastric junction distensibility.

Sensitivity to acid perfusion and distension.

Level of esophageal stasis.

Widt/diameter of the esophagus.

Study description

Background summary

Achalasia is a rare motility disorder of the esophagus that is characterised by aperistalsis of the esophageal body and dysrelaxation of the lower esophageal sphincter (LES). Current treatment is palliative and the aim of the treatment is to diminish the obstructive function of the esophagogastric junction (EGJ). Due to this approach the most frequent complication post-treatment is gastroesophageal reflux (GER). However, not every treated patient develops GER symptoms and the mechanism behind the occurence of GER in treated achalasia are unclear.

Study objective

To investigate the underlying mechanisms of gastroesophageal reflux and gastroesophageal reflux symptoms in treated achalasia patients.

Study design

A prospective observational study.

Study burden and risks

Five different measurements will be performed in two subsequent days. Study

subjects will undergo an EndoFLIP, an acid perfusion test, combined high-resolution manometry (HRM) and pH-impedance monitoring and finally a timed barium esophagography will be performed. At the beginning of the study participants will be asked to fill in questionnaires. The measurements are standard procedures that are routinely performed at the Motility Centre of the Gastoenterology Department in the evaluation of achalasia patients. The associated complications are minimal and mainly caused by the placement of the catheters. The catheters can give discomfort in the nose and pharynx. Furthermore in rare cases a mucosal bleeding of the nose, caused by the catheter, can occur which never need extra treatment.

Study subjects will receive 150 euro for study participation, to cover work day loss. The risks of the measurements are minimal for the study subject. The results of the study have no consequences for the participants and do not influence the treatment or the prognosis of the disease. The study will give insight in the mechanisms behind GER-related symptoms in treated achalasia which is important for the management of these symptoms and potentially have consequences for the choice of the initial treatment for achalasia in newly diagnosed patients. Because the risks for the study subjects in this study are minimal and the results of the study can give valuable new information it is justified to perform this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Treated achalasia patients WITH gastroesophageal reflux symptoms
1) Diagnosis of idiopathic achalasia confirmed by esophageal manometry that shows the following criteria:
- Aperistalsis or simultaneous contractions in the esophageal body.
- LES dysrelaxation.
2) Treatment of achalasia with one of the following procedures:
- Endoscopic balloon dilatation
- Surgical Heller myotomy
- Per-oral endoscopic myotomy (POEM)
3) Minimum total score on the GastroEsophageal Reflux Disease Questionnaire (GERDQ) of * 8.
4) Gastroesophageal symptoms after treatment lasting more than 3 months.
5) Age 18-80 years.
6) Written informed consent.;Treated achalasia patients WITHOUT gastroesophageal reflux symptoms
1) Diagnosis of idiopathic achalasia confirmed by esophageal manometry that shows the following criteria:
- Aperistalsis or simultaneous contractions in the esophageal body.
- LES dysrelaxation.
2) Treatment of achalasia with one of the following procedures:
- Endoscopic balloon dilatation
- Surgical Heller myotomy
- Per-oral endoscopic myotomy (POEM)
3) Maximum total score on the GastroEsophageal Reflux Disease Questionnaire (GERDQ) of < 8.
4) No gastroesophageal symptoms after treatment.
5) Age 18-80 years.
6) Written informed consent.

Exclusion criteria

Treated achalasia patients WITH gastroesophageal reflux symptoms
- Pseudoachalasia.
- Upper gastrointestinal malignancy.
- Chagas disease.

- Peptic ulcer disease.
- Inability to stop PPI, H2-receptor antagonist or prokinetic drug for two weeks.
- Presence of an extremely dilated oesophagus body >5 cm.;Treated achalasia patients WITHOUT gastroesophageal reflux symptoms
- Pseudoachalasia.
- Upper gastrointestinal malignancy.
- Chagas disease.
- Peptic ulcer disease.
- Inability to stop PPI, H2-receptor antagonist or prokinetic drug for two weeks.
- Presence of an extremely dilated oesophagus body >5 cm.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	30-01-2013
Application type:	First submission
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: 20979
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42367.018.12
OMON	NL-OMON20979