Reflux symptoms in patients with achalasia.

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The aim of the study is to investigate the underlying mechanisms of gastroesophageal reflux and gastroesophageal reflux symptoms in treated achalasia patients. It is hypothesized that gastroesophageal reflux symptoms in treated patients with...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20979

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Achalasia, gastroesophageal reflux symptoms, post-treatment.
Achalasie, gastro-oesophageale refluxklachten, post behandeling.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam
Overige ondersteuning: Academic Medical Center (AMC) AMsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Gastroesophageal reflux episodes.

Toelichting onderzoek

Achtergrond van het onderzoek

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 occurrence of GER in treated achalasia is unclear. Understanding this mechanism is important for further treatment of these symptoms and could have consequences for the choice of the initial treatment for achalasia. Therefore, the aim of this study is to investigate the underlying mechanisms of GER and GER symptoms in treated achalasia patients.

Adult treated achalasia patients with and without GER symptoms are included. The required sample size is calculated at 40 study subjects, 20 treated achalasia patients with GER symptoms will be compared to 20 treated achalasia patients without GER symptoms. The primary outcome is gastroesophageal reflux episodes. Secondary outcomes are LES pressure, esophagogastric junction distensibility, sensitivity to acid perfusion and distensibility, level of esophageal stasis and the width/diameter of the esophagus. In two subsequent days five measurements will be performed an EndoFLIP, an acid perfusion test, esophageal high resolution manometry, pH-impedance monitoring and at the end a barium esophagogram. Furthermore at baseline, symptom and quality of life questionnaires will be administered. The measurements are standard procedures that are routinely performed at the motility center of the Gastroenterology department in the evaluation of achalasia patients. Further follow-up after the two study days is not required.

Recruiting country: the Netherlands.

Doel van het onderzoek

The aim of the study is to investigate the underlying mechanisms of gastroesophageal reflux and gastroesophageal reflux symptoms in treated achalasia patients. It is hypothesized that gastroesophageal reflux symptoms in treated patients with achalasia are dependent on retention and fermentation of food due to a reduced clearance by aperistalsis of the esophageal body rather than the result of true acid reflux episodes.

Onderzoeksopzet

At baseline study subjects will have to fill in four questionnaires:

1. SF-36;

2. Achalasia-DSQoL;

3. GerdQ;

4. Eckardt score.

During two subsequent days, starting at baseline, five different measurements will be performed. Some measurements will be performed partly simultaneous. The measurements will be performed in the following order:

First day:

1. Impedance planimetry using Endo Functional Luminal Imaging Probe (EndoFLIP);

2. Bernstein test (acid perfusion test);

3. High Resolution Manometry (HRM);

4. 24-hour pH-impedance monitoring partly simultaneous with the HRM measurement.

Second day:

4. 24-hour pH-impedance monitoring;

5. Timed barium esophagography.

Onderzoeksproduct en/of interventie

Study subjects will have to fill in four questionnaires (SF-36, Achalasia-DSQoL, GerdQ and Eckardt score) and will undergo five different measurements in two following days.

The following measurements will be performed:

1. Impedance planimetry using Endo Functional Luminal Imaging Probe (EndoFLIP);

2. Bernstein test (acid perfusion test);

3. High Resolution Manometry (HRM);

4. 24-hour pH-impedance monitoring;

5. Timed barium esophagography.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Group I - Treated achalasia patients with gastroesophageal reflux symptoms:

1. Diagnosis of idiopathic achalasia confirmed by esophageal manometry that shows the following criteria:

A. Aperistalsis or simultaneous contractions in the esophageal body;

B. LES dysrelaxation.

2. Treatment of achalasia with one of the following procedures:

A. Endoscopic balloon dilatation;

B. Surgical Heller myotomy;

C. Per-Oral Endoscopic Myotomy (POEM).

3. Minimum total score on the GastroEsophageal Reflux Disease Questionnaire (GERDQ) of 8 or higher;

4. Gastroesophageal symptoms after treatment lasting more than 3 months;

5. Age 18-80 years;

6. Written informed consent.

Group II - Treated achalasia patients without gastroesophageal reflux symptoms:

1. Diagnosis of idiopathic achalasia confirmed by esophageal manometry that shows the following criteria:

A. Aperistalsis or simultaneous contractions in the oesophageal body;

B. LES dysrelaxation.

2. Treatment of achalasia with one of the following procedures:

A. Endoscopic balloon dilatation;

B. Surgical Heller myotomy;

C. Per-Oral Endoscopic Myotomy (POEM).

3. Maximum total score on the GastroEsophageal Reflux Disease Questionnaire (GERDQ) of below 8;

4. No gastroesophageal symptoms after treatment;

5. Age 18-80 years;

6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Group I - Treated achalasia patients with gastroesophageal reflux symptoms:

1. Pseudoachalasia;

2. Upper gastrointestinal malignancy;

3. Chagas disease;

4. Peptic ulcer disease;

5. Inability to stop PPI, H2-receptor antagonist or prokinetic drug for two weeks;

6. Presence of an extremely dilated oesophagus body >5 cm.

Group II - Treated achalasia patients without gastroesophageal reflux symptoms:

1. Pseudoachalasia;

2. Upper gastrointestinal malignancy;

3. Chagas disease;

4. Peptic ulcer disease;

5. Inability to stop PPI, H2-receptor antagonist or prokinetic drug for two weeks;

6. Presence of an extremely dilated oesophagus body >5 cm.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-02-2013
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37315
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3654
NTR-old	NTR3838
CCMO	NL42367.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37315

Resultaten

Samenvatting resultaten
N/A