Effect of citalopram on chest pain in patients with achalasia

No registrations found.

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

Summary

ID

NL-OMON23216

Source
Nationaal Trial Register

Brief title
CiPA

Health condition

Achalasia

Sponsors and support

Primary sponsor: Amsterdam UMC (location AMC)
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Primary outcome is the global assessment of reduction of chest pain after 6 weeks of treatment.

Secondary outcome

- Symptom frequency and symptom severity score (calculated from symptom diary)
- Health-related Quality of life (SF-36)
- Achalasia-specific health-related quality of life (Ach-HRQL)
- Hospital Anxiety and depression scale (HADS)
- Adverse events/ complications/ side-effects
- Patients estimation about the received treatment (‘’Which treatment did you think you’ve received?’’)

Study description

Background summary

Achalasia is a motility disorder of the esophagus. Disappearance of myenteric neurons in the esophageal wall leads to failure of relaxation of the lower esophageal sphincter (LES) and impaired peristalsis. Symptoms of achalasia include dysphagia, regurgitation, chest pain and weight loss due to the stasis of food and liquids in the esophagus. There is no cure for achalasia, the treatment focuses on decreasing the resting pressure of the LES to improve esophageal emptying. This can be achieved by pneumodilatation, surgical myotomy or per-oral endoscopic myotomy (POEM); all are safe and effective treatments for patients with achalasia. These treatments effectively diminish the symptoms dysphagia and regurgitation, however have little effect on the occurrence of chest pain. The management of recurrent chest pain in achalasia patients is challenging as 1) the underlying mechanism of chest pain in achalasia is unknown and 2) evidence-based pharmacological options are currently not available. Antidepressants are used in the treatment of pain-predominant functional disorders such as fibromyalgia, irritable bowel syndrome and several functional esophageal disorders including pain in achalasia. Antidepressants modulate esophageal sensation and reduce functional chest pain, however, although these are often prescribed this has not been studied in patients with achalasia.

Study objective

Citalopram will reduce chest pain in patients with achalasia.

Study design

Two visits:
Visit 1: Baseline, Information, Informed Consent, Randomization
Treatment: 6 weeks of citalopram or placebo. Patients will be asked, throughout the whole study, to write down the frequency and the severity each symptom episode.
Visit 2: End of study

Intervention

During the study period of six weeks, patients will either receive daily 20 mg of citalopram or

a placebo.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Written informed consent
- Minimum age: 18 years. Maximum age: 75 years.
- Diagnosed with achalasia type 1 or 2, confirmed by high-resolution manometry
- Previously treated with pneumodilatation, Heller’s myotomy or POEM
- ≥3 months post-treatment for achalasia
Recurrent chest pain
o Midline chest pain or discomfort that is not of burning quality
o At least 3 episodes per week of unexplained chest pain, for a minimum of 3 months.
o No significant stasis, defined as <2cm stasis after 5 minutes on timed barium esophagram
o At start of symptoms, no sign of reflux esophagitis on last esophagogastroduodenoscopy

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Achalasia type 3 (‘’spastic type’’) or spastic contractions on high-resolution manometry
- Surgery of the esophagus except Heller’s myotomy and POEM
- Currently using antidepressants
- Chest pain suspect of cardiac origin.

- Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders)
- Pregnancy or lactation. A pregnancy test will be carried out prior to inclusion in the study. Female patients who are premenopausal and have a negative pregnancy test should be on an anticonceptive.
- Medication-related (contraindication for placebo or citalopram)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	48
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48367
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7779
CCMO	NL69476.018.19
OMON	NL-OMON48367

Study results