Effect of citalopram on chest pain in patients with achalasia

Gepubliceerd: 04-06-2019 Laatst bijgewerkt: 15-05-2024

Citalopram will reduce chest pain in patients with achalasia.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23216

Bron
NTR

Verkorte titel
CiPA

Aandoening

Achalasia

Ondersteuning

Primaire sponsor: Amsterdam UMC (location AMC)
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Citalopram will reduce chest pain in patients with achalasia.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48367
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten