Effect of citalopram on chest pain in patients with achalasia

Published: 18-04-2019
Last updated: 30-01-2025

This study has been transitioned to CTIS with ID 2024-517701-81-01 check the CTIS register for the current data. To assess the effect of citalopram on chest pain in patients with achalasia and to evaluate the effect of citalopram on esophageal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON48367

Source
ToetsingOnline

Brief title
CiPA

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
'achalasia'' and ''motility disorder esophagus''

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, chest, citalopram, pain

Outcome measures

Primary outcome

• Global assessment of chest pain after 6 weeks of treatment with citalopram.

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)

• Symptom severity and time to perception during esophageal acid perfusion and

during esophageal barostat balloon distension test (sub-study).

• Adverse events/ complications/ side-effects

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

This study has been transitioned to CTIS with ID 2024-517701-81-01 check the CTIS register for the current data.

To assess the effect of citalopram on chest pain in patients with achalasia and to evaluate the effect of citalopram on esophageal sensitivity.

Study design

A single centre, double-blind placebo-controlled randomized trial

Intervention

Daily 20 mg of citalopram or a placebo for a period of 6 weeks.

Study burden and risks

We evaluate that treatment with citalopram on chest pain in patients with achalasia is effective and safe. Citalopram is already prescribed for achalasia patients with functional chest pain (off-label). This study is comparable with daily clinical practice only now set up in a placebo-controlled randomized trial. The burden of participating patients will be one extra hospital visit, filling out questionnaires two times and report their chest pain in a symptom diary during the treatment period of six weeks. The dose of citalopram in this study is 20 mg, which is a low dose for adults. Therefore, it is associated with no or only minor side effects. No extra investigations are necessary, for all other investigations are part of the normal work-up for these patients except the tests described in the optional sub-study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Written informed consent
Minimum age: 18 years
Diagnosed with achalasia type 1 or 2
Previously treated with pneumodilatation, Heller*s myotomy or POEM
>=3 months post-treatment for achalasia
Recurrent chest pain

Exclusion criteria

Achalasia type 3 (**spastic type**)
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)
Medication-related (contra-indications for citalopram)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2019
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	citalopram
Generic name:	citalopram
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	05-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-08-2019
Application type:	Amendment
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: 23216
Source: NTR
Title:

In other registers

Register	ID
EU-CTR	CTIS2024-517701-81-01
EudraCT	EUCTR2019-001202-14-NL
CCMO	NL69476.018.19