Effect of citalopram on chest pain in patients with functional chest pain

Published: 21-07-2021
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To assess the effect of citalopram on symptoms of chest pain in patients with functional chest pain.

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

Summary

ID

NL-OMON50787

Source
ToetsingOnline

Brief title
Ci-FCP

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
'functional chest pain' and 'chest pain with unkown origin'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chest, citalopram, functional, pain

Outcome measures

Primary outcome

Global assessment of patient reported reduction in chest pain after 6 weeks of treatment.

Secondary outcome

Global assessment of patient reported reduction in chest pain after 12 weeks of treatment.

Symptom severity and frequency

Health status and quality of life (SF-36)

Psychological comorbidity (HADS)

Adverse events/side effects

Study description

Background summary

Chest pain can be divided in cardiac or non-cardiac chest pain (NCCP). To establish the diagnosis NCCP, acute coronary disease has to be ruled out first. NCCP can be caused by functional chest pain (FCP). NCCP in the absence of musculoskeletal abnormalities, major esophageal motor disorders, gastroesophageal reflux or eosinophilic esophagitis is called FCP. The pathophysiology is not fully understood. Most likely multiple factors play a role, such as esophageal hypersensitivity and enhanced perception. Citalopram and other antidepressants are proven to be effective in the treatment of functional gastrointestinal disorders such as irritable bowel syndrome. However, available data regarding low dose antidepressants in functional chest pain is inconclusive. Moreover, all current evidence concerning the effect of low dose antidepressants in patients with functional chest pain is extracted from trials that pooled patients with different functional esophageal disorders.

Study objective

To assess the effect of citalopram on symptoms of chest pain in patients with functional chest pain.

Study design

A single center, double-blind placebo-controlled randomized trial.

Intervention

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

Study burden and risks

Citalopram has been studied extensively in the past decades, mainly for its use in major depressive disorders. Citalopram is an antidepressant in the group of selective serotonin reuptake inhibitors (SSRIs). In addition to its effect as antidepressant the effect of citalopram in functional gastrointestinal disorders such irritable bowel disease has also been proven. Citalopram and other SSRIs are frequently being prescribed off-label in the same dosage in patients with functional chest pain making the risk of this study negligible over routine clinical care. 20 mg of citalopram is a low dose, so only minor side effects are being expected.

The burden for the participating patients consists of one extra visit to the hospital, 2 phone calls, filling-out questionnaires at the start, after 6 weeks and at the end of the study, and filling-out a daily symptom diary. Stopping therapy without tapering off the antidepressant may result in withdrawal symptoms such as headaches, nausea, sweating or insomnia. The chance of developing withdrawal symptoms is higher after long term use of antidepressants. Since we only treat the patients for twelve weeks, we estimate this as low risk. However, patients will be instructed to contact the investigators when these symptoms occur after ceasing treatment.

In conclusion, citalopram and other SSRIs are already being used off-label in patients with functional chest pain, however a randomized controlled trial never has been done. Therefore there is no additional risk for patients participating in this study compared to daily clinical practice. No additional investigations are needed before patients can participate since all investigations are already done as part of clinical routine

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

* Written informed consent
* Minimum age: 18 years
* Functional chest pain according to Rome IV criteria
* Ruled out cardiac origin of chest pain
* ECG with corrected QT interval (QTc) within the normal range (<450ms male, <460ms female)
* Symptoms of chest pain for at least 6 months
* Frequency of symptoms at least once a week
* Gastroduodenoscopy, high-resolution manometry and 24-hour pH-impedance monitoring need to have been performed recently.

Exclusion criteria

* Currently using antidepressants
* Contraindication for the use of SSRI

* Already tried antidepressants off-label to treat chest pain
* Known allergy to citalopram
* Severe and clinically unstable concomitant disease
* Pregnant, lactating or fertile women (without contraception)

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:	Recruitment stopped
Start date (anticipated):	17-01-2022
Enrollment:	54
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:	21-07-2021

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2021
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-002288-24-NL
CCMO	NL77673.018.21