Effect of amitriptyline in functional heartburn.

Published: 05-02-2013
Last updated: 02-12-2024

Amitriptyline ameliorates heartburn complaints in functional heartburn patients by modulating visceral perception.

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

Summary

ID

NL-OMON20475

Source
Nationaal Trial Register

Health condition

functional heartburn

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: AMC Amsterdam

Intervention

Outcome measures

Primary outcome

Esophageal sensitivy to acid perfusion (perfusion-related symptom score).

Secondary outcome

1. Time to symptoms during esophageal acid exposure;

2. Symptom severity during esophageal acid exposure (visual analog scale or VAS);
3. GERD symptom score improvement after an 8 week treatment with amitriptyline (GERDQ questionnaire, RDQ questionnaire, SF-LDG questionnaire);
4. Quality of life assessment (GERD-QoL questionnaire);
5. Psychological state and anxiety assessment (HADS and SF12 questionnaire).

Study description

Background summary

Many of the patients presenting with typical reflux symptoms who do not respond to the current standard of care (i.e. proton pump inhibition), do not have gastro-esophageal reflux disease. Functional heartburn is an important differential diagnosis in this respect, and can be confirmed or excluded by performing a 24h pH/impedance recording: patients with functional heartburn do not have pathological acid reflux and the symptom-reflux association analysis is typically negative. The management of functional heartburn is often challenging as evidence-based pharmacological options are not available. The use of visceral pain modulators such as tricyclic antidepressants is generally accepted, even though the clinical trials to support their use are likewise lacking. The aim of the current trial is to validate the use of amitriptylin in functional heartburn and to study its mechanism of action.

Study objective

Amitriptyline ameliorates heartburn complaints in functional heartburn patients by modulating visceral perception.

Study design

6 and 20 weeks after start of compound.

Intervention

Amitriptylin 25-50 mg daily or placebo for 6 weeks in a crossover design.

Contacts

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Eligibility criteria

Inclusion criteria

1. Minimum age: 18 years;
2. Documented functional heartburn:
A. Negative esophagogastroduodenoscopy and no history of reflux esophagitis;
B. Negative 24h pH/impedance recording (physiological acid exposure time) and negative symptom association probability.

Exclusion criteria

1. Surgery of the esophagus;
2. Motility disorders of the GI tract leading to delayed gastric emptying or altered intestinal motility;
3. Use of any medication with a potential effect on upper gastrointestinal motility and/or sensitivity that can not be stopped for the duration of the study. If this medication can be stopped, it should be discontinued for at least 2 weeks before the start of the study;
4. Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders);
5. 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;
6. Medication-related:
A. Contra-indications for amitriptyline use: epilepsy, organic central nervous system disorders, prostate hypertrophy, pyloric stenosis, cardiovascular disease, hyperthyroidism, liver- and kidney function impairment;
B. Interaction can occur with barbiturates, carbamazepine, ketoconazol and ritonavir . Concommitant use of MAO-inhibitors is contra-indicated.
7. Hypersensitivity to the active substance or to any of the excipients.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	21
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38685
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3673
NTR-old	NTR3843
CCMO	NL43405.018.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38685

Study results

Summary results
N/A