Effect of amitriptyline in functional heartburn.

Gepubliceerd: 05-02-2013 Laatst bijgewerkt: 02-12-2024

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

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

Samenvatting

ID

NL-OMON20475

Bron
Nationaal Trial Register

Aandoening

functional heartburn

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: AMC Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

6 and 20 weeks after start of compound.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Meibergdreef 9
A.J. Bredenoord
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661745

Wetenschappelijk

Meibergdreef 9
A.J. Bredenoord
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661745

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	21
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38685
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A