A double-blind, placebo controlled, randomized study comparing the effects of amitriptyline on dyspeptic symptoms in patients with functional dyspepsia.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25161

Source
NTR

Brief title
the amitriptyline studie

Health condition

functional dyspepsia

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam, Department gastroenterology
Source(s) of monetary or material Support: Academic Medical Center (AMC) Amsterdam

Intervention

Outcome measures

Primary outcome

To determine the therapeutical effects of amitriptyline in patients with functional dyspepsia by disease specific questionnairres.

Secondary outcome

1. Which subgroup of patients with functional dyspepsia, stress sensitive or NOT stress sensitive, have the best benefits for the treatment with amitriptyline?
2. Does stress plays a role in the degree of the therapeutic effects?
3. What is the therapeutical effect on the seperate dyspeptic symptoms?

Study description

Background summary

Treatment: amitriptyline 1 dd 25 mg or placebo for 8 weeks. After 2 weeks of treatment there will be an evaluation of the medications and if necessary the doses changes to 1 dd 12.5 mg or 1 dd 50 mg.
Before start of treatment patients will get a drinking test, gastroscopie, stress profile by CPS and IAPS, and some questionnaires. During treatment patients get only questionnaires and at the end of the 8 weeks the drinking test will be repeat and the overall treatment effect will be determined.

Study objective

What is the therapeutical effect of amitriptyline in patients with functional dyspepsia? And have stress-sensitive patients more benefit than NOT stress-sensitive patients.

Intervention

1. Amitriptyline 1dd 12.5 mg or 25 mg or 50 mg or placebo;
2. Drinking test;
3. Stress profile (CPS and IAPS);
4. Questionnaires.

Contacts

Public
Academic Medical Center (AMC), Department of Gastroenterology, C2-328,
P.O. Box 22660
G.E.E. Boeckxstaens
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667375
Scientific
Academic Medical Center (AMC), Department of Gastroenterology, C2-328,
P.O. Box 22660
G.E.E. Boeckxstaens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667375

Eligibility criteria

Inclusion criteria

1. Age 18-65 years;
2. Functional dyspepsia (NDI>25);
3. No effect on PPI, or 3 months constantly the same dose of PPI;
4. No medications which influence the intestine;
5. No depression (ZUNG < 50).

Exclusion criteria

1. Gastroduodenal surgery in history;
2. Reflux-like dyspepsia (Rome II criteria);
3. Use of anitdepressivants;
4. Organic abnormalities;
5. Severe cardiac, renal, pulmonary, hepatic or systemic diseases;
6. Hyperthyroidism;
7. Glaucoma and epilepsy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	220
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL582
NTR-old	NTR638
Other	: N/A
ISRCTN	ISRCTN76116512

Study results

Summary results
N/A