

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

Submission date 08/05/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/05/2006	Overall study status Completed	☐ Protocol
Last Edited 11/01/2021	Condition category Digestive System	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NL582, NTR638

Study information

Scientific Title

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

Acronym

The amitriptyline study

Study objectives

What is the therapeutical effect of amitriptyline in patients with functional dyspepsia? Have stress-sensitive patients more benefit than non stress-sensitive patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not received as of 08/05/2006.

Primary study design

Interventional

Study design

A double-blind, placebo controlled, randomized study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Functional dyspepsia

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Amitriptyline

Primary outcome(s)

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

Key secondary outcome(s)

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 separate dyspeptic symptoms?

Completion date

01/05/2009

Eligibility

Key inclusion criteria

1. Age 18-65 years
2. Functional dyspepsia (Nepean Dyspepsia Index [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)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

38

Key exclusion criteria

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

Date of first enrolment

01/05/2006

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Center (AMC), Department of Gastroenterology (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

University/education

Funder Name

Academic Medical Center (AMC)

Alternative Name(s)

Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011	11/01/2021	Yes	No