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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

Registration date
08/05/2006

Overall study status
Completed

Last Edited
11/01/2021

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
A double-blind, placebo controlled, randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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?

Overall study start date
01/05/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
220

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)

Sponsor details
P.O. Box 22660
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Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Center (AMC)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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