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Dyspepsia - amitriptyline: effect of amitriptyline on dyspeptic symptoms assessed with the drink test in patients with functional dyspepsia

Submission date 04/08/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/08/2005	**Overall study status** Stopped	
Last Edited 11/06/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR47

Study information

Scientific Title
Effect of amitriptyline on dyspeptic symptoms assessed with the drink test in patients with functional dyspepsia

Study objectives
To assess the effect of amitriptyline on dyspeptic symptoms assessed with the drink test in patients with functional dyspepsia.

Please note that as of 8th May 2006: This trial did not go ahead. It was started again with a different design. The new trial is registered under ISRCTN76116512, http://www.controlled-trials.com/ISRCTN76116512.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Non-randomised controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional dyspepsia

Interventions
Subjects will receive 25 mg amitriptyline (25 mg) or placebo once a day (QD) for 6 weeks.
The dose will be doubled to 50 mg QD when there is no effect of the lower dose.
In case of adverse events the dose will be halved to 12.5 mg QD.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amitriptyline

Primary outcome(s)
Patient will undergo a drink test before and after treatment. Dyspepsia symptoms will be assessed again after treatment using the Nepean Dyspepsia Index. At the end of the trial subjects are asked to fill out the Subject's Global Assessment (SGA), a Quality of Life questionnaire and the Zung score.

Key secondary outcome(s)
Not provided at time of registration

Completion date

01/06/2008

Eligibility

Key inclusion criteria
1. Nepean Dyspepsia Index (NDI) score greater than or equal to 25
2. No depression according to Zung questionnaire
3. Aged greater than 18 and less than 65 years
4. Drugs known to affect gastrointestinal (GI) motility should be stopped at least 24 hours prior to the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Reflux-like dyspepsia (Rome II criteria)
2. Unable to stop drug intake (see inclusion criteria)
3. Use of tricyclic antidepressants
4. Organic abnormalities explaining the dyspeptic complaints encountered during endoscopy or abdominal ultrasound
5. Epilepsy
6. Organic brain damage
7. Urine retention
8. Prostatic hyperplasia
9. Pyloric stenosis
10. Cardiovascular disorders
11. Hyperthyroidism, liver- and kidney-function disorders

Date of first enrolment
01/06/2005

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration