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

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

**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**
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

### Study design
Non-randomised controlled parallel group trial

### Primary study design
Interventional

### Secondary study design
Non 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
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 measure
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.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/06/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
65 Years

### Sex
Both

### Target number of participants
100

### 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
Netherlands
1105 AZ

## Sponsor information

### Organisation
Academic Medical Centre (AMC) (The Netherlands)

### Sponsor details
Emma Kinderziekenhuis
Postbus 22660
Amsterdam
Netherlands
1105 AZ

### Sponsor type
University/education

### Website
http://www.amc.uva.nl/

### ROR

https://ror.org/03t4gr691

# Funder(s)

**Funder type**
University/education

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