

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

<b>Submission date</b> 04/08/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/06/2008	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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