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 |
| Registration date | Overall study status | Statistical analysis plan |
| 04/08/2005 | Stopped | Results |
| Last Edited | Condition category Digestive System | ☐ Individual participant data |
| 11/06/2008 | | Record updated in last year |

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

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

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

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

1105 AZ

Study participating centre Meibergdreef 9 Amsterdam Netherlands

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