

Dyspepsia - Amitriptyline.

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25606

Source

NTR

Brief title

N/A

Intervention

Study description

Background summary

Patiënt 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 SGA (Subject's Global Assessment), a Quality of Life questionnaire and the Zung score.

Study objective

N/A

Intervention

Subjects will receive 25 mg Amitriptyline (25 mg) or placebo 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Nepean Dyspepsia Index (NDI) score ≥ 25 ,
2. no depression according Zung questionnaire,
3. > 18 and < 65 years of age,
4. drugs known to affect GI motility should be stopped at least 24 hours prior to the study.

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,
12. liver- and kidneyfunction disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-06-2005
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL27
NTR-old	NTR47
Other	: N/A
ISRCTN	ISRCTN87452036

Study results