Evaluation of the mucosa-permeability of the stomach measured by the Ussing Chambers technique in patients with functional dyspepsia before and after treatment with amitriptyline.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20933

Source
NTR

Brief title
Substudy 2: permeability

Health condition

Functional dyspepsia.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam, department of gastroenterology
Source(s) of monetary or material Support: Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

To show that the permeability of the mucosa in stomach and duodenum is increased in (stress-sensitive) patients with functional dyspepsia.

Secondary outcome

1. Is there a difference between healthy volunteers and patients with functional dyspepsia?

2. Amitriptyline has a positive effect on the mucosa permeability by reducing the level of stress and the dyspeptic symptoms will be improved.

Study description

Background summary

Patients who will take part to the amitriptyline study will get biopsy (6) during gastroscopy before the start of the amitriptyline study. 40 of the patients who join this substudy will get another gastroscopy with biopsy (6) at the end of the amitriptyline study. The biopsy will be analysed by using the Ussing chambers technique.

20 Healthy volunteers will get only one gastroscopy with biopsy (6).

Study objective

Through stress the mast cells become activated and by their vaso-active substances the mucosa permeability will become increased. Therefore the mucosa is easier to penetrated by microbes and acid. This increased permeability will leads to hypersensitivity, inflammation and pain.

Study design

N/A

Intervention

1. Patients: amitriptyline or placebo (see amitriptyline study);

2. Gastroscopy with biopsy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-65 years;

2. Patients have to take part in the amitriptyline study;

3. Functional dyspepsia (NDI>25);

4. No depression (ZUNG<50);

5. No effect of PPI or 3 months constantly the same doses;

6. No medications which influence the intestine.

Exclusion criteria

1. Gastroduodenal surgery in history;

2. Reflux-like dyspepsia (Rome II criteria);

3. Use of antidepressants;

4. Organic abnormalities;

5. Severe cardiac, renal, pulmonary, hepatic, or systemic diseases. Hyperthyroidism, glaucoma and epilepsy.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2006
Enrollment:	60
Type:	Actual

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	NL602
NTR-old	NTR658
Other	: N/A
ISRCTN	ISRCTN53060944

Study results

Summary results
N/A