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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

Submission date 07/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/06/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/09/2011	**Condition category** Digestive System	[_] Individual participant data [_] 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
N/A

Study information

Scientific Title

Study objectives
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 penetrate by microbes and acid. This increased permeability will lead to hypersensitivity, inflammation and pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomized controlled 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 (FD)

Interventions
1. Patients: amitriptyline or placebo (see amitriptyline study)
2. Gastroscopy with biopsy

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amitriptyline

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

Secondary outcome measures
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

Overall study start date
01/05/2006

Completion date
01/05/2006

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Patients have to take part in the amitriptyline study (ISRCTN76116512)
3. Functional dyspepsia (Nepean dyspepsia index [NDI] >25)
4. No depression (Zung self-rating depression scale <50)
5. No effect on proton pump inhibitor (PPI), or a constant three-month dosage of PPI
6. No medications which will influence the intestine

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Key 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

Date of first enrolment
01/05/2006

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC), Department of Gastroenterology (The Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
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Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Center (AMC)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
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