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.

Gepubliceerd: 24-03-2006 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20933

Bron
NTR

Verkorte titel
Substudy 2: permeability

Aandoening

Functional dyspepsia.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam, department of gastroenterology
Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

2. Gastroscopy with biopsy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2006
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL602
NTR-old	NTR658
Ander register	: N/A
ISRCTN	ISRCTN53060944

Resultaten

Samenvatting resultaten
N/A