Esophageal epithelial permeability changes
in patients with allergic esophagitis.

Gepubliceerd: 06-06-2012 Laatst bijgewerkt: 15-05-2024

The pathophysiology of eosinophilic esophagitis (EoE) is largely unknown. We hypothesize that in EoE an impaired epithelial barrier due to acidic reflux could result in a deep penetration of food antigens into the epithelium and subsequent...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28827

Bron
Nationaal Trial Register

Aandoening

Eosinophilic esophagitis, pathophysiology, etiology, epithelial barrier integrity, permeability.
Eosinofiele oesofagitis, pathofysiologie, etiologie, epitheliale barrierefunctie, permeabiliteit.

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam, The Netherlands
Overige ondersteuning: Netherlands Organisation for Scientific Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Size of esophageal epithelial intercellular spaces in EoE patients and healthy controls;
2. Permeability of esophageal mucosa to small molecules in EoE patients and healthy

controls;
3. Tissue impedance of esophageal epithelium (in vivo) in EoE patients and healthy controls;
4. Numbers of esophageal intraepithelial mast cells and eosinophils in EoE patients and healthy controls.

Toelichting onderzoek

Achtergrond van het onderzoek

The pathophysiology of EoE is largely unknown. We hypothesize that in EoE an impaired epithelial barrier due to acidic reflux could result in a deep penetration of food antigens into the epithelium and subsequent processing and activation of antigen presenting cells followed by activation of an inflammatory Th2 response.

Therefore, epithelial barrier function in EoE patients will be measured using several modalities and compared to epithelial barrier function of healthy controls. Furthermore, the effect of 8 weeks of proton pump inhibition on the epithelial barrier function will be determined in EoE patients.

Doel van het onderzoek

The pathophysiology of eosinophilic esophagitis (EoE) is largely unknown. We hypothesize that in EoE an impaired epithelial barrier due to acidic reflux could result in a deep penetration of food antigens into the epithelium and subsequent processing and activation of antigen presenting cells followed by activation of an inflammatory Th2 response. Evidence for an acid-induced impaired epithelial barrier in EoE will significantly contribute to our understanding of the pathophysiology of this disorder and therefore will be helpful for the development of an acceptable therapy.

Onderzoeksopzet

All parameters are measured at baseline in EoE patients and healthy controls.

Measurements are repeated in EoE patients after 8 weeks of treatment with esomeprazole.

Onderzoeksproduct en/of interventie

Eosinophilic esophagitis patients are treated with esomeprazole 40 mg bd for 8 weeks.

The controls will receive no treatment.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eosinophilic esophagitis group:

1. Previous diagnosis of EoE confirmed by histopathology e.g. presence of >15 eosinophilic granulocytes per high power field (hpf) in mid-esophageal biopsies before the start of any therapy;

2. Written informed consent;

3. Age 18 – 75 years.

Healthy control group:

1. Written informed consent;

2. Age 18 – 75 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Eosinophilic esophagitis group:

1. Inability to stop topical corticosteroids;

2. Inability to stop PPI, H2-receptor antagonist or prokinetic drug for 8 weeks;

3. Use of systemic corticosteroids, leukotriene inhibitors, or monoclonal antibodies, in the two month period preceding the study;

4. Use of anticoagulants;

5. Use of NSAIDs;

6. History of peptic ulcer disease;

7. History of Barrett’s esophagus;

8. History of GI cancer;

9. History of GI tract surgery (except appendectomy);

10. ASA class IV or V.

Healthy control group:

1. Use of systemic corticosteroids, leukotriene inhibitors, or monoclonal antibodies;

2. Use of anticoagulants;

3. Use of NSAIDs;

4. Personal history of atopic, skin or systemic diseases;

5. Symptoms suggestive of esophageal disease;

6. History of GI cancer;

7. History of GI tract surgery (except appendectomy);

8. History of PPI, H2-receptor antagonist, or prokinetic drug use;

9. ASA class IV or V.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-09-2011
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-06-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36166
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3347
NTR-old	NTR3480
CCMO	NL36704.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36166

Resultaten

Samenvatting resultaten
N/A