

Effects of topical steroids in patients with eosinophilic esophagitis (EoE).

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An impaired epithelial barrier function is suggested to play a role in the pathophysiology of EoE. Standard treatment with topical corticosteroids results in a reduction of symptoms and esophageal eosinophilia. We hypothesize that by treating EoE...

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

Samenvatting

ID

NL-OMON25172

Bron

Nationaal Trial Register

Aandoening

Eosinophilic esophagitis, etiology, pathophysiology, epithelial barrier function, permeability, steroids, treatment, therapy.

Eosinofiele oesofagitis, etiologie, pathofysiologie, epitheliale barrierefunctie, permeabiliteit, steroiden, behandeling, therapie.

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam, The Netherlands

Overige ondersteuning: Academic Medical Center, Amsterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tissue impedance, intercellular spaces, and mucosal permeability to small molecules before and after treatment with 500 µg fluticasone propionate twice daily for 8 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

An impaired epithelial barrier function is suggested to play a role in the pathophysiology of EoE. Standard treatment is with topical corticosteroids. EoE patients will be treated with swallowed fluticasone aerosole for 8 weeks. Endoscopy will be performed at baseline and after steroid therapy, to determine the effect on several epithelial barrier function parameters and eosinophilia.

Doel van het onderzoek

An impaired epithelial barrier function is suggested to play a role in the pathophysiology of EoE. Standard treatment with topical corticosteroids results in a reduction of symptoms and esophageal eosinophilia. We hypothesize that by treating EoE patients with swallowed fluticasone propionate, the esophageal epithelial barrier function could be restored. The effect of topical corticosteroid therapy on the epithelial barrier function has never been investigated before.

Onderzoeksopzet

At baseline and after 8 weeks of treatment with fluticasone.

Onderzoeksproduct en/of interventie

EoE patients will be treated with fluticasone 500 mcg bd for 8 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inability to stop PPI, H2-receptor antagonist or prokinetic drug for 8 weeks;
2. Use of systemic corticosteroids, leukotriene inhibitors, or monoclonal antibodies, in the two month period preceding the study;
3. Use of anticoagulants;
4. Use of NSAIDs;
5. History of Barrett's esophagus;
6. History of upper GI tract surgery;
7. ASA class IV or V.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	29-02-2012
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-06-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37559
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3355
NTR-old	NTR3487
CCMO	NL39184.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37559

Resultaten

Samenvatting resultaten

N/A