

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25172

### Source

Nationaal Trial Register

### Health condition

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

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

## Sponsors and support

**Primary sponsor:** Academic Medical Center, Amsterdam, The Netherlands

**Source(s) of monetary or material Support:** Academic Medical Center, Amsterdam, The Netherlands

## Intervention

## Outcome measures

### Primary outcome

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

## Secondary outcome

Numbers of esophageal intraepithelial eosinophils and mast cells before and after treatment with 500 µg fluticasone propionate twice daily for 8 weeks.

## Study description

### Background summary

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.

### Study objective

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.

### Study design

At baseline and after 8 weeks of treatment with fluticasone.

### Intervention

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

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	29-02-2012
Enrollment:	12
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	18-06-2012
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 37559  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

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

## Study results

### Summary results

N/A