

# Individually tailored Dietary treatment of Eosinophilic oesophagitis in Adults

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To demonstrate that food elimination therapy based on component-resolved diagnostics is an effective and acceptable treatment for EoO patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39630

### Source

ToetsingOnline

### Brief title

IDEA-study

## Condition

- Gastrointestinal inflammatory conditions
- Allergic conditions

### Synonym

allergic esophagitis, Eosinophilic esophagitis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Diet, Dysphagia, Eosinophilic esophagitis, Therapy

## Outcome measures

### Primary outcome

Oesophageal eosinophilic infiltration at baseline and after dietary treatment, and after reintroduction of foods, as measured by the peak eosinophil count in the oesophageal mucosa.

### Secondary outcome

Symptoms of dysphagia and quality of life (SF-36 and the FAQLQ-AF questionnaire), endoscopic signs of EoO, oesophageal mastocytic infiltration, serum levels of biomarkers for EoO (eosinophil count, total IgE, IL-5, IL-13, eotaxin-3, eosinophil derived neurotoxin [EDN]), oesophageal tissue biomarkers (e.g. IL-5, IL-13, eotaxin-3, periostin, TGF- $\beta$ , filaggrin, phospho-MLCK).

Validation of results of the ImmunoCAP ISAC allergy test compared to standard skin prick test results.

## Study description

### Background summary

Eosinophilic oesophagitis (EoO) is an inflammatory disease of the oesophagus resulting in dysphagia, food impaction and strictures. Current treatment is limited to topical or systemic corticosteroids, dietary measures and repeated endoscopic dilations. The use of corticosteroids is accompanied by increased risks of infections and metabolic disorders such as osteoporosis while dilations have a substantial perforation risk.

We have already found that an impaired barrier function of the oesophageal epithelium plays a role in the pathophysiology of EoO, enabling passage of molecules with the size of food allergens through the epithelium and possibly causing immune activation. Since most EoO patients suffer from atopic diseases,

it has been suggested that food allergens play a role in EoO. We believe that these food allergens can cross the epithelial barrier and therefore hypothesize that a diet based on broad-spectrum food allergen testing could decrease inflammation and reduce symptoms.

### **Study objective**

To demonstrate that food elimination therapy based on component-resolved diagnostics is an effective and acceptable treatment for EoO patients.

### **Study design**

Prospective proof of principle study.

### **Intervention**

Exclusion diet based on allergy test

### **Study burden and risks**

Burden and risk: Endoscopy with biopsy taking and blood sampling will be performed three times. Endoscopy is associated with a very low risk of perforation. Skin prick tests may lead to anaphylaxis; for this reason these tests will be performed by an experienced clinical allergologist in the AMC. Benefit: Patients will be tested for allergies using techniques that are not (yet) available for routine clinical care and will consult an allergy specialist dietician to get dietary advice based on this result.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- \* Previous clinical diagnosis of EoO confirmed by histopathology e.g. presence of >15 eosinophilic granulocytes per high power field (hpf) in mid- or proximal-oesophageal biopsies
- \* (Cross-)sensitization against at least 1 food allergen as measured by ImmunoCAP ISAC
- \* Age 18-75 years
- \* Written informed consent

### Exclusion criteria

- \* Inability to stop previously started topical or systemic corticosteroids, leukotriene inhibitors, or monoclonal antibodies, in the two month period preceding and during the study
- \* Use of NSAIDs
- \* History of peptic ulcer disease
- \* History of Barrett's oesophagus
- \* History of GI cancer
- \* History of GI tract surgery (except appendectomy or cholecystectomy)
- \* ASA class IV or V

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2013
Enrollment:	40
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	03-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

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

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL42608.018.12