Behandeling met een op maat gemaakt dieet bij eosinofiele oesofagitis: “De IDEA-studie”

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27096

Source
Nationaal Trial Register

Brief title
IDEA-study

Health condition

Eosinophilic oesophagitis, food allergy, diet, ImmunoCAP ISAC, serum IgE.
Eosinofiele oesofagitis, voedselallergie, dieet, ImmunoCAP ISAC, serum IgE.

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

Peak eosinophilia in mucosal biopsies of proximal, mid- and distal oesophagus at baseline

and after targeted dietary treatment defined as complete (peak eosinophil count, <5 eos/hpf), near complete (<10 eos/hpf), and partial (>50% reduction of peak eosinophil count).

Secondary outcome

• Symptoms of dysphagia;

• Quality of life, as measured by the SF-36 and the FAQLQ-AF questionnaire;

• Endoscopic signs of EoO;

• Peak mastocytosis in mucosal biopsies of proximal, mid- and distal oesophagus;

• Serum levels of biomarkers for EoO: eosinophil count, total IgE, IL-5, IL-13, eotaxin-3, eosinophil derived neurotoxin (EDN);

• RNA-expression of biomarkers for EoO in oesophageal tissue;

• Evaluation of dietary intake at baseline of EoO-patients

• Comparison of results of the ImmunoCAP ISAC allergy test with 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.

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.

Study population: patients diagnosed with EoO (≥15 eosinophils per HPF) aged 18-75 yrs with confirmed IgE-antibodies to at least 1 food allergen.

Intervention: in all patients with EoO and observed sensitization to aeroallergens and/or food allergens, a diet with exclusion of all foods to which the patient is sensitized is started. At baseline, after 6 weeks of dietary treatment and 6 weeks after reintroduction of foods, patients will undergo endoscopy with biopsies, and blood sampling, and they will fill in symptom questionnaires.

Main study parameters/endpoints:
Primary: 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: Symptoms of dysphagia and quality of life (SF-36 and the FAQLQ-AF questionnaire), endoscopic signs of EoO, oesophageal mastocytic infiltration, EoO biomarkers in serum and oesophageal tissue; validation of results ImmunoCAP ISAC allergy test results compared to standard skin prick test results.

Study objective

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 design

t=0: stop immunosuppressants

t=8wks: endoscopy, start diet

t=14wks: endoscopy, food reintroduction

t=20wks: endoscopy, skin prick testing

Intervention

Baseline endoscopy, followed by food elimination diet during 6 weeks and re-endoscopy. In responders, foods will be reintroduced during 6 weeks, followed by a third endoscopy

Contacts

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Eligibility criteria

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 (microarray)

• 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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-06-2013
Application type:	First submission

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
NTR-new	NL3890
NTR-old	NTR4052
Other	Individually tailored Dietary treatment of Eosinophilic oesophagitis in Adults : METC-nr: NL42608.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A