

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

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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...

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

Samenvatting

ID

NL-OMON27096

Bron

Nationaal Trial Register

Verkorte titel

IDEA-study

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam, The Netherlands

Overige ondersteuning: Academic Medical Center, Amsterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

t=0: stop immunosuppressants

t=8wks: endoscopy, start diet

t=14wks: endoscopy, food reintroduction

t=20wks: endoscopy, skin prick testing

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

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:	01-07-2013
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-06-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A