Effect of Amino acid formula on esophageal inflammation and intestinal permeability in adult Eosinophilic esophagitis patients

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To study the effect of Neocate elemental nutrition on the esophageal eosinophilic inflammation in adult patients with eosinophilic esophagitis. Secondary: to study the effect of Neocate elemental nutrition on esophageal and intestinal mucosal...

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

Samenvatting

ID

NL-OMON23046

Bron
NTR

Verkorte titel
“IMAGE trial”

Aandoening

Eosinophilic esophagitis, treatment, elemental diet, amino acid based formula, eosinophils, gastrointestinal barrier function

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam, The Netherlands
Overige ondersteuning: Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in esophageal mucosalpeak eosinophil count, measured as maximum number of eosinophils per hpf. Response is defined as complete when the peak eosinophil count decreases to <15 eos/hpf.

Toelichting onderzoek

Achtergrond van het onderzoek

Eosinophilic esophagitis (EoE) is an increasingly encountered disease for which yet no acceptable medical treatment exists. There is sufficient evidence to state that food allergy plays an important role in EoE and dietary treatment has proven efficacy in these patients. It has been suggested that elemental nutrition is an effective treatment for these patients. In this trial we will study the effect of Neocate elemental nutrition on the esophageal eosinophilic inflammation in adult patients with eosinophilic esophagitis. Furthermroe we will study the effect of Neocate elemental nutrition on esophageal and intestinal mucosal integrity, esophageal inflammation, endoscopic signs, symptoms and quality of life, and the gastrointestinal microbiome in these patients.The EoE patients will consume an elemental diet for 4 weeks. Baseline upper endoscopy with tissue impedance measurements is performed and esophageal & duodenal biopsies are taken in EoE patients and healthy volunteers. Symptoms, quality of life, and product acceptability are being investigated using questionnaires. Furthermore, the intestinal barrier function will be measured using a dual sugar method by calculating lactulose:mannitol (L:M) ratio and saliva and feces are collected to optionally assess the indigenous microbiota. In EoE patients, these measurements are repeated after 4 weeks of elemental nutrition.

Doel van het onderzoek

To study the effect of Neocate elemental nutrition on the esophageal eosinophilic inflammation in adult patients with eosinophilic esophagitis. Secondary: to study the effect of Neocate elemental nutrition on esophageal and intestinal mucosal integrity, esophageal inflammation, endoscopic signs, symptoms and quality of life, and the gastrointestinal microbiome in these patients.

Onderzoeksopzet

The EoE patients will consume an elemental diet for 4 weeks. Baseline upper endoscopy with tissue impedance measurements is performed and esophageal & duodenal biopsies are taken in EoE patients and healthy volunteers. Symptoms, quality of life, and product acceptability are being investigated using questionnaires. Furthermore, the intestinal barrier function will

be measured using a dual sugar method by calculating lactulose:mannitol (L:M) ratio and saliva and feces are collected to optionally assess the indigenous microbiota. In EoE patients, these measurements are repeated after 4 weeks of elemental nutrition.

Onderzoeksproduct en/of interventie

Elemental diet preceded by and followed by gastroscopy, vena puncture, salive, feces and urine analysis.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Previous diagnosis of EoE confirmed by histopathology e.g. presence of >15 eosinophilic granulocytes per high power field (hpf) in mid or proximal esophageal biopsies before the start of any therapy

- Currently experiencing dysphagia

- Written informed consent

- Age 18 – 75 years

Healthy controls:

- Written informed consent

- Age 18 – 75 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients:

- Inability to stop topical corticosteroids

- Use of systemic corticosteroids, leukotriene inhibitors, or monoclonal antibodies, in the month preceding the study

- Use of anticoagulants at study entry

- Use of NSAIDs without possibility to stop

- History of peptic ulcer disease

- History of Barrett’s esophagus

- History of GI cancer

- History of GI tract surgery (except appendectomy)

- ASA class IV or V

Healthy controls:

- Use of systemic corticosteroids, leukotriene inhibitors, or monoclonal antibodies in the month preceding the study

- Use of anticoagulants at study entry

- Use of NSAIDs without possibility to stop

- Personal history of atopic, skin or systemic diseases

- Symptoms suggestive of esophageal disease

- History of GI cancer

- History of GI tract surgery (except appendectomy)

- History of PPI, H2-receptor antagonist, or prokinetic drug use

- ASA class IV or V

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-11-2014
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-11-2014
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	NL4687
NTR-old	NTR4892
Ander register	: Dossiernummer NL49502.018.14, ABR Nummer49502

Resultaten