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

No registrations found.

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

Summary

ID

NL-OMON23046

Source
NTR

Brief title
“IMAGE trial”

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam, The Netherlands
Source(s) of monetary or material Support: Nutricia Research

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Measures of mucosal barrier function:

- Esophageal and duodenal permeability measured in vivo (electrical tissue impedance spectroscopy) and ex vivo (Ussing chambers experiments)

- Intestinal permeability testing using a PEG absorption

– Urine excretion test

Clinical parameters:

- Questionnaires

- Symptoms (dysphagia, food impaction) (Baseline and after 4 week)

- Patient acceptation of and adherence to the diet (every week)

- Quality of life (SF-36) Baseline and after 4 weeks

- Endoscopic features

- Correlation between primary/secondary parameters and intestinal permeability

- Adherence to the diet

- Empty drink packages will be stored by the patient and they will be asked to note the date of consumption on it

- A questionnaire “Studie productinname” will be filled in weekly

Laboratory investigations:

- Immunohistochemical analyses of esophageal and duodenal biopsy material to assess expression and localization of proteins involved in barrier function

- Serum biomarkers (total IgE, eosinophil count, IL-5, IL-13, eotaxin-3, eosinophil-derived neurotoxin)

- Transcriptional analyses: microarray or focused qPCR. Genes to be analyzed by qPCR involve:

- Activity markers of EoE (IL-5, IL-13, eotaxin-3, TGF-B)

- Tight junction proteins (Claudins, ZO-3, occludin, filaggrin, desmoglein)

- Inflammatory genes (IL-6, IL-10, TNFá, CCL-2, CCL-5, CCL-20, LAG3, ICAM1, caspases 1-14)

- If other assessments show differences between the groups optionally the gastrointestinal microbiome will be analyzed.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2014
Enrollment:	14
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-11-2014
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	NL4687
NTR-old	NTR4892
Other	: Dossiernummer NL49502.018.14, ABR Nummer49502

Study results