Effect of addition of elemental nutrition to an elimination diet on esophageal inflammation in adult eosinophilic esophagitis (EoE) patients: A randomized controlled trial

No registrations found.

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

Summary

ID

NL-OMON24372

Source
Nationaal Trial Register

Brief title
Supplemental Elemental trial (SET)

Health condition

Eosinophilic oesofagitis
Elimination diet
Elemental supplement
Esophageal inflammation

In het Nederlands
Eosinofiele oesofagitis
Eliminatie dieet
Elementair supplement
Oesofagiale inflammatie

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam. Dept. Gastroenterology & Hepatology
Source(s) of monetary or material Support: Nutricia Research

Intervention

Outcome measures

Primary outcome

Change in peak eosinophil count, measured as maxi mum number of eosinophils per HPF. Response is defined as complete if the
reduction of absolute number of eosinophils per HPF is decreased to <10 eosinophils/HPF. Esophageal mucosal eosinophil
infiltration is considered the most important marker of disease activity and is primary endpoint in all major therapeutic studies. These
biopsies are taken at mid and proximal esophageal level during upper endoscopy.

Secondary outcome

Clinical / endoscopic parameters:

- Questionnaires:

o o Patient accep tation of and adherence to the diet will be checked by means of an appointment at the dietitian after 2 and 4 weeks
to evaluate
the diet. Fea sibility of the diet will be measured using the likert scoring system.

o Patient reported symptoms (EEsAI, Reflux Disease Questionnaire (RDQ), Ga strointestinal complaints questionnaire and
Straumann Dysphagia Index (SDI))) (baseline and after diet)

o Quality of life (EoE-QoL-A) (baseline and after diet)

o Esophageal endoscopic signs measured with the E ndoscopic Reference Score (EREFS)

- Nutritional monitoring:

o Body Mass Index (BM I) to measure weight loss

o Nutrition intake will be calculated at baseline an d after 4 weeks of elimination diet using 3-day food diaries

Laboratory investigations:

- Expression of genes enc oding for the esophageal inflammation and barrier function (IL-1, IL-4, IL-6, IL-8, IL10, IL12, IL-13, IL-15,
Thymic
Stromal Lymphopoietin (TSLP), Eotaxin (CCL26), desmoglein-1 (DSG1) and filaggrin (FLG))

- Immunohistochemical analyses of esophageal material to assess expression and localizatio n of proteins involved in barrier
function.

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

o Activity markers of EoE (IL-5, IL-13, eotaxin-3, TSLP)

o Barrier integrity proteins (filaggrin, desmoglein)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

The extra burden of participation in the study is limited to one extra visit to the hospital and filling out questionnaires. Eliminatio n diet
is an accepted treatment for EoE and is accompanied by regular endoscopy to evaluate each dietary step. There are no extra risks
associated with the addition of elemental nutrition.

Study description

Background summary

Rationale: There is sufficient evidence to state that food allergy plays an important role in eosinophilic esophagitis (EoE), and dietary treatment has proven efficacy in these patients. Elimination diets and elemental nutrition with amino acid-based formula are effective but both also have limitations. Combination of elimination diets with amino acid-based nutrition might improve adherence, prevent weight loss and increase the feasibility of the elimination diet. Furthermore, there is data suggesting that amino acid-based nutrition has anti-inflammatory effects itself, aside from the removal of all disease triggering food allergens. We hypothesize that the addition of amino acid-based nutrition to a four food elimination diet (FFED) is more effective than a FFED alone due to the: (1) anti-inflammatory effect of the amino acids and (2) increased feasibility of allergen avoidance.

Objectives: Primary: To evaluate whether, in adult EoE patients, the addition of an elemental (amino acid-based) nutrition to the FFED is more effective in decreasing the esophageal

eosinophilic inflammation and increasing the dietary acceptability and patients' adherence than a FFED alone.

Study design: Prospective randomized controlled trial

Study population: Adult EoE patients with proven active disease (>15 eosinophils per high power field (HPF))

Intervention: EoE patients are treated with a FFED alone or with a FFED with addition of amino acid-based nutrition for 6 weeks. Baseline upper endoscopy is performed and esophageal biopsies are taken for histological and transcriptional analyses before and after 6 weeks diet. Diet acceptability and adherence, symptoms and quality of life are being investigated using questionnaires. Body Mass Index (BMI) is calculated and all measurements are repeated after 6 weeks of dietary treatment.

Main study parameters/endpoints: Reduction of esophageal eosinophilic inflammation with FFED compared with FFED with addition of elemental (amino acid-based) nutrition. Secondary endpoints are acceptability of the treatment, quality of life and symptoms.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Following an elimination diet can be a burden for adults. The risk of the performed procedures consists of the very small risk of biopsies, namely bleeding and perforation. The study will evaluate the effectiveness of a new dietary approach in EoE and contribute to better understanding of this condition.

Study objective

To evaluate whether the addition of amino-acid based nutrition to FFED is superior to FFED alone in terms of improvement of the esophageal eosinophilic inflammation, and improved patients' adherence and acceptability of the diet. Secondary, it will be important to study the effect of additional amino acid-based nutrition on symptoms as measured by patient reported outcomes, weight loss prevention and quality of life. In both arms the efficacy of the intervention will be controlled for the total composition of the diet.

Study design

12 months

Intervention

FFED v.s. FFES with addition of elemental nutrition

Contacts

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Eligibility criteria

Inclusion criteria

- Active EoE at baseline i.e. 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

Exclusion criteria

- Inability to stop topical corticosteroids

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

- Use of anticoagulants at study entry

- Recent history of GI cancer

- History of major GI tract sur gery

- ASA class IV or V

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2017
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-10-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48882
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6014
NTR-old	NTR6778
CCMO	NL62715.018.17
OMON	NL-OMON48882

Study results