

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

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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...

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

Samenvatting

ID

NL-OMON24372

Bron

NTR

Verkorte titel

Supplemental Elemental trial (SET)

Aandoening

Eosinophilic oesofagitis
Elimination diet
Elemental supplement
Esophageal inflammation

In het Nederlands
Eosinofiele oesofagitis
Eliminatie dieet
Elementair supplement
Oesofagiale inflammatie

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam. Dept. Gastroenterology & Hepatology

Overige ondersteuning: Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in peak eosinophil count, measured as maximum 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

12 months

Onderzoeksproduct en/of interventie

FFED v.s. FFES with addition of elemental nutrition

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 surgery
- ASA class IV or V

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	20-10-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48882
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten