Hypersensitivity in Eosinophilic Esophagitis

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1. To investigate esophageal sensitivity to acid infusion and balloon distension in eosinophilic esophagitis patients with histological active disease and disease in remission, as compared to healthy controls 2. To investigate the difference in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON49677

Source
ToetsingOnline

Brief title
SENSEoE-trial

Condition

- Gastrointestinal inflammatory conditions

Synonym
allergic esophagitis, Eosinophilic esophagitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Eosinophilic esophagitis, Hypersensitivity, Mucosal Integrity, Sensitivity tests

Outcome measures

Primary outcome

Measures of sensitivity of the esophagus:

1. Perfusion sensitivity scores in histological active disease, disease in remission and healthy controls, calculated via [(total perfusion time * lag time to perception) x maximum VAS]

2. Balloon pressure that induced a sensation of discomfort in histological active disease, disease in remission and healthy controls

Secondary outcome

1. Esophageal barrier function in histological active disease and disease in remission, defined as electrical tissue impedance measured with ETIS and transepithelial electrical resistance and fluorescein flux measured in Ussing chamber

2. The degree of reflux in the EoE patients, as measured with 24-hours pH-impedance measurement

Study description

Background summary

Eosinophilic esophagitis (EoE) is chronic inflammatory condition of the esophagus, characterized by symptoms of esophageal dysfunction, such as

dysphagia and food impactions. Different treatment options are available for EoE patients, such as acid suppressive medication, dietary treatment and topical steroids. One study suggests that EoE patients with active disease are more sensitive to physiological quantities of acid. We would like to investigate if the observed hypersensitivity also exists in patients with histological disease in remission. One of the problems of treating EoE patients is that in some patients symptoms persists after histological remission has been achieved. We wonder if persistent hypersensitivity explains why some patients with histological disease in remission remain symptomatic. In the present study we would further elucidate presence of hypersensitivity in EoE and its relation to the esophageal mucosal integrity.

Study objective

1. To investigate esophageal sensitivity to acid infusion and balloon distension in eosinophilic esophagitis patients with histological active disease and disease in remission, as compared to healthy controls
2. To investigate the difference in esophageal sensitivity to acid infusion and balloon distension between eosinophilic esophagitis patients with histological disease in remission who remain symptomatic and patients that are histological and clinical in remission
3. To investigate the relationship between esophageal sensitivity and mucosal integrity
4. To investigate the presence of GERD and its influence on the sensitivity to acid perfusion and on mucosal integrity

Study design

Prospective, single centre study

Intervention

An acid perfusion test and barostat balloon distention test will be performed in EoE patients at baseline. This will be repeated in the EoE patients after 6-8 weeks of topical budesonide standard treatment. To investigate the relationship between the esophageal sensitivity and the mucosal integrity in EoE patients a gastroscopy will be conducted, in which ETIS is performed and biopsies are taken for the Ussing chambers. In order to investigate the potential influence of concurrent GERD, EoE patients undergo a 24-Ph impedance measurement.

Study burden and risks

The burden of participation in this study is a total of 4 visits for EoE patients. Gastroscopy with biopsies is a routinely performed, safe investigation to evaluate disease activity in EoE patients. Patients are not

exposed to additional risks, however, the duration of the procedure is slightly extended due to the ETIS and additional biopsies taken. Balloon distention test and acid perfusion test are commonly used for assessing esophageal sensitivity, no complication have been described. Participants will be compensated financially for participation in the study and the findings could help us better understand symptom perception in eosinophilic esophagitis patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Previous diagnosis of active EoE confirmed by histopathology e.g. presence of >15 eosinophilic granulocytes per high power field (hpf) in esophageal biopsies
- Written informed consent

- Age 18-75 years

Exclusion criteria

- Any form of treatment for EoE (topical corticosteroids, PPI or dietary treatment) in the month preceding the study
- ASA class III, IV or V
- The need for pain medication 24 hours before the visit

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2020
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	31-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL72089.018.19