Serum allergens and innate lymphoid cells in eosinophilic esophagitis.

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Primary: to analyze serum samples of adult EoE patients for IgE reactivity to recombinant allergens of common foods.Secondary: to demonstrate the presence of ILC2 in periferal blood of adult patients with eosinophilic esophagitis Tertiary: To store...

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

Summary

ID

NL-OMON35461

Source
ToetsingOnline

Brief title
Serum allergens and ILCs in EoE

Condition

- Gastrointestinal inflammatory conditions
- Allergic conditions

Synonym
(idiopathic) eosinophilic esophagitis, Allergic 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: Allergens, Eosinophilic, Esophagitis, ILCs

Outcome measures

Primary outcome

- IgE reactivity to recombinant allergens of common foods and inhalants in

adult EoE patients.

Secondary outcome

- The number of ILC2 cells in periferal blood of adult EoE patients.

- Biomarkers for disease activity of eosinophilic esophagitis before and after

8 weeks of standard PPI treatment.

Study description

Background summary

Eosinophilic esophagitis (EoE) is a recently recognized disorder characterized by an abnormal accumulation of eosinophils in the esophageal mucosa in patients with symptoms of dysphagia and esophageal food impaction which typically requires repeated emergency endoscopies to remove impacted food. Long-term presence of the disorder leads to fibrotic strictures and diffuse narrowing in the esophagus that require endoscopic dilatations with a risk of perforation.
A potential allergic pathway in the pathophysiology of this disorder is suggested by the observation that a large proportion of EoE patients has an atopic constitution. Estimates of IgE mediated food hypersensitivity in patients with EoE range from 15 to 43%.
Hypoallergenic foods and medical treatment with corticosteroids are effective, but the disease almost always recurs upon discontinuation. Furthermore, treatment with topical or systemic corticosteroids is accompanied by various side-effects and therefore less suitable for long-term use.

Diagnosis is currently based on symptoms and abnormal histopathology, requiring endoscopy to take biopsies. No studies have been published that would clearly permit diagnosis on biomarkers. Furthermore, no reliable biomarker of inflammation has been identified yet, necessitating endoscopy to confirm control over the inflammatory process after treatment. Possible future

biomarkers include serum eotaxin-3, plasma basic fibroblast growth factor and serum IL-15. Results on this subject are shortly expected from current U.S. studies.

The family of innate lymphoid cells (ILCs) is emerging as a group of critical players in innate immunity and tissue remodeling. Recently, a new member of the ILC family, termed ILC2, was identified. This cell type produces very high levels of the cytokines IL-5 and IL-13, known to be involved in allergy and EoE. Since ILC2 produce high amounts of IL-5 and IL-13, these cells may contribute to the pathology of EoE.

Study objective

Primary: to analyze serum samples of adult EoE patients for IgE reactivity to recombinant allergens of common foods.

Secondary: to demonstrate the presence of ILC2 in periferal blood of adult patients with eosinophilic esophagitis

Tertiary: To store serum for future studies aimed at determining biomarkers for eosinophilic esophagitis before and after 8 weeks of standard PPI treatment.

Study design

This observational cohort study has a prospective design. The duration of the study will be three years.

EoE patients will donate 30 mL of blood off treatment and 10 mL after 8 weeks of standard PPI treatment
- For future identification of biomarkers for disease and clinical response to therapy, venous blood samples will be drawn twice in all patients; once off treatment and once after 8 weeks of standard PPI treatment. In this context, 10 mL of serum will be immediately stored.
- For analysis of food specific IgE, two Sarstedt serum probes of 5 mL will be collected once and stored.
- For isolation of circulating ILC2, 10 mL of serum is collected once.
Initially, analysis of ILC2 will be performed in 10 patients. When ILC2 cannot be found in the peripheral circulation of these patients, analysis will not be performed in the other patients. The number of ILC2 will be determined immediately in 5 mL of serum. The other 5 mL will be stored for further analysis on this subject.

Study burden and risks

Participating in this study results in blood withdrawal either through the infusion needle which is already in situ for endoscopy, or through vana

puncture. The extent of the burden is considered minimal. Blood withdrawal is associated with only a slight risk of bleeding/hematoma, infection or thrombophlebitis.

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 EoE confirmed by histopathology e.g. presence of >15 eosinophilic granulocytes per high power field (hpf) in mid-esophageal biopsies
* Written informed consent
* Age 18 * 75 years

Exclusion criteria

* 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

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

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	NL37677.018.11