An intervention study to improve therapeutic compliance in adult patients with eosinophilic esophagitis.

Published: 08-11-2022
Last updated: 27-04-2024

To assess the effects of additional education in combination with more frequent follow up and patient reminders on adherence to treatment in adult EoE patients.

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

Summary

ID

NL-OMON51510

Source
ToetsingOnline

Brief title
EoE compliance

Condition

- Gastrointestinal inflammatory conditions

Synonym
allergic esophagitis, Eosinophilic esophagitis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,bedrijf,Dr. Falk Pharma Benelux BV

Intervention

Keyword: Compliance, Eosinophilic esophagitis, Intervention, Maintenance treatment

Outcome measures

Primary outcome

Differences in treatment adherence between both groups after 12 weeks, 6 months and 12 months.

Secondary outcome

- Differences in self-reported treatment adherence (measured by MARS questionnaire, 8-point MMAS, BMQ, IPQ) after 12 weeks, 6 months and 12 months.

- Change in clinical symptoms (measured by SDI, DSQ) after 12 weeks, 6 months and 12 months.

Study description

Background summary

In many chronic conditions adherence to long-term treatment is a challenge, also for patients with eosinophilic esophagitis. Interventions, such as behavioral, educational and reminder interventions might improve treatment adherence.

Study objective

To assess the effects of additional education in combination with more frequent follow up and patient reminders on adherence to treatment in adult EoE patients.

Study design

A single center, prospective, randomized, two-armed, blinded controlled trial.

Intervention

Subjects will be randomized into either the intervention group, in which subjects will receive additional education in combination with more frequent follow up and patient reminders, or the control group.

Study burden and risks

The burden of participation will be two additional hospital visits, filling out questionnaires (not psychologically stressful) and 5 follow-up calls. There are no risks involved in this study.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Written informed consent
- Male or female patient
- Age >18 years
- Previous diagnosis of EoE, confirmed by histopathology, with the presence of >15 eosinophilic granulocytes per high power field (hpf) in esophageal biopsies
- Current maintenance treatment for EoE with a PPI or swallowed topical corticosteroids or about to start with these maintenance medications as decided during regular clinical practice

Exclusion criteria

- Severe and clinically unstable concomitant disease that may interfere with the subject*s ability to participate in the study
- Receive investigational treatment during the study
- Dilation of esophagus required
- Insufficient Dutch or English language skills to understand patient information leaflets

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2023
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2022
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	NL82384.018.22