Contractile segment impedance as a marker for active inflammation in eosinophilic esophagitis in children

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to assess the diagnostic accuracy of CSI (at 5, 10 and 15 cm proximal to the upper border of the lower esophageal sphincter) for the presence of active disease and/or complete remission in pediatric EoE.

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

Summary

ID

NL-OMON55028

Source
ToetsingOnline

Brief title
CSI-EOE

Condition

- Gastrointestinal inflammatory conditions

Synonym
esophageal inflammation provoked by food protein

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting kindermotiliteit Nederland

Intervention

Keyword: contractile segment impedance, eosinophilic esophagitis, marker, non-invasive

Outcome measures

Primary outcome

Diagnostic test accuracy of CSI to assess *active disease* or *complete remission* compared to reference standard (EGD with histology).

Secondary outcome

• To establish the change in CSI with changing inflammation

• To calculate inter- and intrarater variability of CSI

• To establish a cut-off value for (change in) CSI for the presence / absence of EoE

• To perform a cross-validation

• To assess the patient burden of patients and parents of CSI and esophagogastroduodenoscopy and compare them.

• Cost-effectiveness assessment

Study description

Background summary

Eosinophilic esophagitis (EoE) is a chronic inflammation of the esophagus that is triggered by ingestion of food proteins. The current gold standard for the diagnosis and follow-up of EoE is esophagogastroduodenoscopy (EGD) with at least 6 biopsies. During follow up, symptoms are well known not to correlate with histological disease severity and therefore, frequent EGD with biopsies are needed for evaluation of treatment success and/or to tailor treatment. EGD*s in children are not only invasive by nature, but are performed under general anesthetics. A less invasive test for the diagnosis and follow-up of EoE, especially in children, is thus desired.

Recently, ''contractile segment impedance' (CSI), an impedance-manometry derived parameter, prooved to be a good marker for the activity of inflammation in other inflammatory processes. Existing data suggests that CSI could be of diagnostic value in EoE.

Study objective

to assess the diagnostic accuracy of CSI (at 5, 10 and 15 cm proximal to the upper border of the lower esophageal sphincter) for the presence of active disease and/or complete remission in pediatric EoE.

Study design

This is a multicenter cross-sectional study in pediatric patients who undergo a routine EGD with biopsies for the diagnosis or follow-up of EoE. These children will be offered an additional impedance-manometry, with calculation of CSI. This will be compared to the clinical histology results.

Study burden and risks

Participants of this study will have all standard care visits and EGD*s for EoE. Apart from standard care, they need to visit the hospital one additional time for CSI assessment during HRIM. HRIM is a very safe procedure. The catheter can give minor discomfort in the nose and pharynx. In rare cases a minor mucosal bleeding of the nose, caused by the catheter, can occur which never needs additional treatment. We have recently shown that this test is very well tolerated in children.(13) Additionally, study participants need to fill out three short questionnaires (less than 10 minutes in total)
Participants will experience no direct benefit from this study, as the clinical decisions in this study will be based on the currently used diagnostics (EGD + histology). However, if our hypothesis will be proven and CSI will become an accepted less invasive test for EoE activity, participants may indirectly benefit from their participation in the future.
The current therapeutic options consist of complex elimination diets, corticosteroids and/or proton pump inhibitors (PPI), depending on the choice of parents and children. Corticosteroids and PPIs have several side effects, especially in children. Despite their known complications, many children and their families choose for PPI or corticosteroid therapy, because the elimination diet (favorable because long-term safety) requires more EGD*s to identify the food protein(s) that triggers EoE. While adults undergo EGD with only mild- or no sedation, children require general anesthesia. HRIM (with CSI measurement) could potentially dramatically reduce the number of EGD*s needed in children with EOE.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Children aged 12-20 years who will undergo an esophagogastroduodenoscopy for the diagnosis or follow-up of EoE.

Exclusion criteria

Inability to speak/understand English (Australia) or Dutch (The Netherlands)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-08-2020
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	high resolution impedance manometry
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-10-2020
Application type:	Amendment
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	NL72872.018.20