CSI as a marker for active EoE

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22247

Source
Nationaal Trial Register

Brief title
CSI-EoE

Health condition

Eosinophilic Esophagitis

Sponsors and support

Primary sponsor: Investigator initiated study by Amsterdam UMC, location AMC
Source(s) of monetary or material Support: Investigator initiated study

Intervention

Outcome measures

Primary outcome

The goal of our study is to assess diagnostic accuracy of CSI and/or change in CSI (at 5, 10 and 15 cm proximal to the upper border of the lower esophageal sphincter) for the presence of persistent active disease in pediatric EoE.
Diagnostic accuracy parameters:
- CSI and/or change in CSI (if applicable)
- EGD histologic results (at least 15 eos/hpf (standard size of ~0.3mm2)
- Positive predictive value, negative predictive value, sensitivity, specificity and likelihood

ratios of CSI for
o Presence of active disease
o Presence of complete remission

Secondary outcome

- Inter- and intrarater variability of CSI
- cross-validation
- assess the patient burden of CSI and esophagogastroduodenoscopy and compare them using the DISCO questionnaire
- cost effectiveness of HRIM vs esophagogastroduodenoscopy

Study description

Background summary

Eosinophilic esophagitis (EoE) is a chronic non IgE-mediated eosinophilic 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. Inflamed mucosa, no matter the origin of inflammation, has a higher permeability and therefore lower resistance to electrical flow, which can be measured using impedance. Recently it was shown, that high resolution impedance manometry (HRIM) can be used for the diagnosis of gastroesophageal reflux disease (GERD), another disease that causes inflammation in the esophagus. The contractile segment impedance (CSI) that was calculated during HRIM, measures impedance at the time of the maximal esophageal contraction to ensure that the esophageal mucosa is measured instead of luminal contents.
In parallel to GERD, CSI could thus be a marker for EoE-state (histological remission or active disease). HRIM parameters are influenced by esophageal length, which significantly correlates with patient's age. As CSI may especially be of added value in children by potentially reducing the number of invasive EGD's, it is necessary to perform this study in a pediatric cohort in order to obtain reliable data on CSI for the pediatric population. High resolution impedance manometry (HRIM) is a minimally invasive procedure that is comparable to placing a nasogastric feeding tube and takes 15 minutes to perform. Patients do not require sedation and we have recently shown that this test is very well tolerated in children.

Study objective

Our hypothesis is that contratile segment impedance is a marker for EoE-disease activity

(histological remission or active disease)

Study design

Study patients will undergo an esophagogastroduodenoscopy for the evaluation of macroscopical and histological endoscopy results. Directly after the EGD, a short questionnaire regarding the burden of the intervention (endoscopy) will be taken. Within 7 days prior/after the endoscopy, a high resolution impedance manometry will be performed to calculate the CSI. Directly after the manometry, the same questionnaire regarding the burden of the intervention (manometry) will be taken in order to compare burden of endoscopy vs manometry.
Positive predictive value, negative predictive value, sensitivity, specificity and likelihood ratios of CSI as well as inter- and intrarater variablility of CSI, cross-validation and cost-effectiveness will be calculated after all study subjects have been included and all endoscopies, manometries and questionnaires have been completed / performed.

Intervention

High resolution impedance manometry (HRIM)

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age 12 years up to 19 years inclusive
- Previous EGD with histological evidence of EoE (15 eosinophils per high power field)

- Need for a routine clinical EGD

Exclusion criteria

Any of the following contraindications for high resolution manometry:
- insufficient knowledge of the Dutch or English language
- Near complete obstruction
- Severe coagulopathy
- Cardiac conditions in which vagal stimulation is poorly tolerated
- Oesophageal varices
- Nasal septum deviation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-08-2020
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	30-07-2020

Application type: First submission

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
NTR-new	NL8850
Other	METC AMC : METC AMC: 2020_043#B2020377; toetsingonline: NL72872.018.20

Study results