

CSI as a marker for active EoE

Gepubliceerd: 30-07-2020 Laatste bijgewerkt: 18-08-2022

Our hypothesis is that contractile segment impedance is a marker for EoE-disease activity (histological remission or active disease)

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22247

Bron

Nationaal Trial Register

Verkorte titel

CSI-EoE

Aandoening

Eosinophilic Esophagitis

Ondersteuning

Primaire sponsor: Investigator initiated study by Amsterdam UMC, location AMC

Overige ondersteuning: Investigator initiated study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Our hypothesis is that contractile segment impedance is a marker for EoE-disease activity (histological remission or active disease)

Onderzoeksopzet

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 variability 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.

Onderzoeksproduct en/of interventie

High resolution impedance manometry (HRIM)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	02-08-2020
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	30-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8850
Ander register	METC AMC : METC AMC: 2020_043#B2020377; toetsingonline: NL72872.018.20

Resultaten