STRICTuring Crohn’s disease assessment using advanced Ultrasound and magnetic REsonance imaging techniques for evaluation of inflammation and fibrosis

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Advanced intestinal ultrasound and MRE techniques could differentiate between inflammatory and fibrotic strictures in Crohn's Disease

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

Samenvatting

ID

NL-OMON24793

Bron
Nationaal Trial Register

Verkorte titel
STRICTURE

Aandoening

Crohn's Disease

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: European Crohn's and Colitis Organisation, International Bowel Ultrasound Group, Amsterdam Gastroenterology & Metabolism

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

MRI:
- MT-ratio
- IVIM fractional perfusion
- T2*-value
- Quantitated intestinal motility

Ultrasound:
- Speed of velocity of shear-wave (m/s)
- Mean transit time of intravascular contrast (s)
- Time to peak (s)
- Blood volume per tissue (mL/100 mL tissue)
- Blood flow (m/s)
- Time between arrival of oral contrast at the stricture and passage through the stricture
- Number of bowel movements before oral contrast passes through the stricture

Clinical:
- Response to therapy after 26 weeks of treatment (defined by the continuation of baseline medical therapy without adding other anti-inflammatory medication, the absence of the need for an intervention (balloon dilation or surgery) and no clinical deterioration based on clinical activity indices9,31)

Histopathology:
- Inflammation grades
- Fibrosis grades

Toelichting onderzoek

Achtergrond van het onderzoek

Bowel stricturing in Crohn's disease (CD) occurs frequently.1 Whereas inflammatory strictures might benefit from anti-inflammatory therapy, fibrotic strictures often need a surgical approach.1,2 However, current imaging biomarkers are unable to adequately determine stricture composition.3

Ultrasound and MRI are frequently used in the evaluation of CD activity.4 Previous studies showed that advanced modalities of both techniques are promising in stricture characterization.3,5 However, data is scarce and most studies did not evaluate the clinical relevance of advanced imaging techniques. Therefore, we will evaluate state-of-the-art cross-sectional imaging parameters to define stricture composition and to assess their clinical value.

Objectives: The primary aims of this study are to evaluate advanced MRI and ultrasounds techniques to:

1. Identify advanced imaging techniques that correlate with stricture composition as defined by the histopathologic degree of fibrosis and inflammation in the resection specimen

2. Identify advanced imaging parameters that distinguish patients responding to anti-inflammatory therapy and patients requiring surgery

Doel van het onderzoek

Advanced intestinal ultrasound and MRE techniques could differentiate between inflammatory and fibrotic strictures in Crohn's Disease

Onderzoeksopzet

Baseline, medication group will receive a second ultrasound and MRE after 26 weeks

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Amsterdam UMC/AMC
Floris de Voogd

020-5661922

Wetenschappelijk

Amsterdam UMC/AMC
Floris de Voogd

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Endoscopic or histological confirmed Crohn’s Disease
• Age ≥ 18 year
• One or more small bowel stricture(s) confirmed on endoscopy and/or cross-sectional

imaging
• Scheduled for anti-inflammatory treatment or surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Isolated colonic stricture
• Endoscopic balloon dilation prior to baseline MRI or ultrasonography
• Pregnancy
• Age <18years
• Inability to give informed consent
• Ongoing gastroenteritis
• No stricture visible on ultrasound and/or MRI
• Specifically for MRI
o General contraindications for MRI (MRI-incompatible implants, pacemaker, claustrophobia, and pregnancy)
• Specifically for CEUS
o Chronic obstructive lung disease
o Acute coronary heart disease
o Clinically unstable heart disease
o Previous allergic reaction to Sonovue or to its components

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2019
Aantal proefpersonen:	54
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-12-2020
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	NL9105
Ander register	METC AMC : METC 2019_168

Resultaten