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

No registrations found.

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

Summary

ID

NL-OMON24793

Source
Nationaal Trial Register

Brief title
STRICTURE

Health condition

Crohn's Disease

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: European Crohn's and Colitis Organisation, International Bowel Ultrasound Group, Amsterdam Gastroenterology & Metabolism

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Conventional MRI parameters: length of the stricture, prestenotic dilatation, bowel wall thickness, bowel wall edema, bowel wall enhancement and stratification, fatty wrapping, presence of lymph nodes, fistulas and abscesses.
- Conventional ultrasound parameters: length of the stricture, prestenotic dilation, bowel wall thickness, wall layer stratification, fatty wrapping, Doppler signal, motility, presence of lymph nodes, abscesses, fistulas.
- Clinical information: medical history, sex, age, weight, height, current and previous medication
- Clinical activity scores: Harvey-Bradshaw Index31 (HBI) and Crohn’s Disease Obstructive Score9 (CDOS)
- Blood: C-reactive protein, hemoglobin, platelet count, leukocyte count, erythrocyte count and albumin
- Faecal calprotectin

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2019
Enrollment:	54
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-12-2020
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	NL9105
Other	METC AMC : METC 2019_168

Study results