Investigating the effects of resolving intestinal narrowing in Crohn's disease – a study of gut bacteria, movement and products

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
26/12/2018		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/02/2019 Last Edited	Completed Condition category	☐ Results		
		Individual participant data		
18/07/2023	Digestive System	Record updated in last year		

Plain English summary of protocol

Background and study aims

Crohn's disease (CD) is a chronic gastrointestinal condition with serious health implications. CD is characterised by the presence of small and large bowel inflammation. CD patients frequently experience abdominal pain, nausea, and diarrhoea. These symptoms may result from 'narrowings' within the bowel known as 'strictures'. Crohn's patients who have intestinal surgery experience 'stricturing' (the formation of strictures) more often.

The 'CS3M Crohn's Stricture Study' will give new insights into 'strictures' in this context. There are many unanswered questions. It is unclear how strictures affect bowel contraction, bacteria within the gut and bacterial by-products. It is also not clear how to best treat patients with strictures.

This study will investigate four separate aspects of intestinal strictures in Crohn's disease:

- 1. How stenting of strictures affects the movement of the bowel (a.k.a. motility).
- 2. How stenting of strictures affects the bacterial content of the gut (a.k.a. microbiome).
- 3. How stenting of the strictures affects bacterial by-products from the gut (a.k.a. metabolomics).
- 4. The clinical impact of CD stricture stenting.

The results from this pilot study may inform future large scale trials involving stenting in CD. This research will generate novel data about stenting impact in CD and will consist of the first global report such findings.

Who can participate?

Only Crohn's disease patients with identified 'intestinal strictures' will be asked to participate. Several different treatment options exist. Intestinal 'stenting' is one of the available therapies. It involves the endoscopic placement of an opening device, known as a 'stent', into the affected area.

Should a patient choose to undergo stent therapy, they will then be asked to take part in the study. Only adult patients (ages 18-80), who can give consent and are not enrolled in other research studies will be eligible. No healthy controls will be enrolled in the study.

What does the study involve?

Each patient will undergo a Magnetic Resonance (MR) scan before and after stent treatment. Stool samples will be collected prior to and following 'stenting'. These stool samples will be analysed for bacterial content and by-products. The techniques used for stool analysis will include bacterial genetic analysis and gas-chromatography analysis of bacterial metabolites. Each patient's clinical progress will be reviewed and assessed with validated Inflammatory Bowel Disease (IBD) scoring tools.

What are the possible benefits and risks of participating?

The risks to each study participant (from stool collection, and MRI scanning) has been deemed to be low. The novel insights into strictures in CD will be delivered by data produced by stool analysis and MRI scans of the intestine. Clinical data will further our understanding of stent treatment in Crohn's disease. Personal research findings will be relayed to study participants.

Where is the study run from?

All study activities will be conducted at a single research centre - Royal Derby Hospital – UK. The study is being sponsored by the University of Nottingham.

When is the study starting and how long is it expected to run for? Beginning from January 2019, the study will run for a total of 18 months.

Who is funding the study?

All study activities are being funded by an internal Royal Derby Hospital - Gastroenterology research fund and a further Royal Derby Hospital charity source.

Who is the main contact?
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Contact information

Type(s)

Public

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Additional identifiers

Integrated Research Application System (IRAS)

252808

Protocol serial number

DHRD/2018/078, IRAS 252808

Study information

Scientific Title

Characterising the effects of relieving stricture obstruction by ileocolonic stenting - a pilot study into motility, microbiomics and metabolomics in Crohn's disease

Acronym

CS3M

Study objectives

The relief of ileocolonic, Crohn's stricture-related mechanical obstruction has a quantifiable impact on bowel motility, the intestinal bacterial population and associated metabolomic profiles.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health and Social Care Research Ethics Committee B (HSC REC B), 24/12/2018, ref. 18/NI/0241

Study design

Pilot observational cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Crohn's Disease.

Interventions

Patients with Crohn's disease and abnormal intestinal 'narrowings' (known as 'strictures') will be asked to take part in the study. Each patient will have routine clinical treatment of their 'stricture' with a removable expanding device. Before and after treatment, specific studies will be performed. Each patient with undergo two intestinal MRI scans examining gut movements. Stool samples will be collected before and following therapy. Each stool sample will be analysed for bacterial content and separate chemical by-products. Patient progress will be monitored

throughout the study. The total time of involvement for each patient will be between 8 to 10 months.

Intervention Type

Other

Primary outcome(s)

- 1. The bowel microbiome will be measured using stool bascterial 16sRNA analysis pre-therapy, during therapy and post-therapy.
- 2. Intestinal motility will be measured using magnetic resonance-assessed small bowel motility at baseline and after 6 weeks of therapy.
- 3. The stool metabolic profile will be measured using gas-chromatography stool metabolomic analysis pre-therapy and post-therapy.
- 4. Clinical impact on Crohn's ileocolonic strictures will be measured using paired assessment with validated IBD scoring tools (CDAI, HBI, IBD-Q) at baseline and at 6-8 weeks.

Key secondary outcome(s))

- 1. Progression onto Surgery
- 2. Recruitment Rate
- 3. Complications / Adverse Events

Completion date

01/01/2021

Eligibility

Key inclusion criteria

- 1. Crohn's Disease as an established diagnosis (established diagnosis based on histology and supportive imaging)
- 2. Previous right hemicolectomy or partial resection and subsequent large and small bowel reanastomosis
- 3. Identified anastomotic or de novo stricture accessible by colonoscopy endoscopic or imaging identification (MR or CT or endoscopy)
- 4. Aged 16-80 years
- 5. Symptoms attributable to a focal ileocolonic stricture
- 6. Ability to give informed consent

Inclusion into the study will only be following Inflammatory Bowel Disease Multidisciplinary Team referral and strict adherence to the given inclusion criteria.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Malignancy
- 2. Significant cardiovascular or respiratory disease
- 3. Uncontrolled thyroid disease
- 4. Neurological or cognitive impairment
- 5. Significant physical disability
- 6. Hepatic disease or renal failure
- 7. Abnormal blood results other than those explained by CD in CD participants
- 8. Co-enrolment in other CD study
- 9. Pregnancy or ongoing breastfeeding
- 10. Any condition that precludes MRI scanning (e.g. pacemaker)
- 11. Routine usage of any medication that affects gastric emptying or small bowel motility (i.e. hyoscine butylbromide, mebeverine, domperidone, ondansetron, metoclopramide)
- 12. Inability to endoscopically access stricture or place stent

Date of first enrolment

10/04/2019

Date of final enrolment

01/03/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Royal Derby Hospital

Uttoxeter Road Derby United Kingdom DE22 3NE

Sponsor information

Organisation

University of Nottingham

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Gastroenterology Departmental Research Fund - Royal Derby Hospital

Funder Name

Charitable Fund - Royal Derby Hospital

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes