Characterising the Effects of Relieving Stricture Obstruction by Ileocolonic Stenting - A Pilot Study into Motility, Microbiomics & Metabolomics in Crohn's Disease
University of Nottingham – Registered Study

SYNOPSIS

Title	**Characterising the Effects of Relieving Stricture Obstruction by Ileocolonic Stenting - A Pilot Study into Motility, Microbiomics & Metabolomics in Crohn's Disease**
Acronym	CS3M Study
Short title	'The Crohn's Stricture CS3M Study' (CS3M Study)
Chief Investigator	**Mr. Jonathan Lund** Associate Professor & Consultant Surgeon University of Nottingham - Health Sciences Department Royal Derby Hospital Uttoxeter Road, DE223NE, Derby
Objectives	The primary aim is to characterise the effect of the stenting of Crohn's ileocolonic (IC) strictures on gut motility, microbiomics and metabolomics.
Trial Configuration	Single centre, prospective cohort study
Setting	University Hospital – Royal Derby Hospital
Sample size estimate	There is no precedent or trial data regarding stricture stenting in Crohn's disease. Given the absence of data on which to base power calculations upon to establish sample size, considerations of feasibility and precision about the mean/variance have guided recruitment. As presented by previous authors a sample size of 12 has therefore been established. (Julious 2005; Connelly 2008; Hertzog 2008) Drop out rate of 10% assumed.
Number of participants	14 (Included patients)
Eligibility criteria	Adult (>18 years old) patients with Crohn's disease who have an identified anastomotic or ileo-caecal stricture. **Inclusion criteria** • Crohn's disease (CD) patients • Previous right hemicolectomy or partial resection and subsequent small bowel re-anastomosis • Identified intestinal OR anastomotic stricture - dual modality identification (MR / Endoscopy) • Age: 16-80 **Exclusion Criteria:** • Malignant disease • Significant cardiovascular or respiratory disease

	• Uncontrolled thyroid disease • Neurological or cognitive impairment • Significant physical disability • Hepatic disease or renal failure • Abnormal blood results other than those explained by CD in CD participants • Co-enrollment in other CD study • Pregnancy or ongoing breastfeeding • Any condition with precludes MRI scanning (e.g. pacemaker) • Routine usage of any medication that affects gastric emptying or small bowel motility (i.e. hyoscine butylbromide, mebeverine, domperidone, ondansetron, metoclopramide) • Idiopathic, non-Crohn's disease strictures • Inability to endoscopically access stricture
Description of interventions	Each patient will undergo a Magnetic Resonance (MR) scan before and after stent treatment. Stool samples will be collected prior to and following stenting.
Duration of study	**Total Study Duration: 18 months** • 12-18 months recruitment / data capture • 6 months post intervention follow up & data analysis **Total Study Duration Per Patient:** 12 Weeks Active Phase, plus Follow Up Phase at 6 months.
Outcome measures	Primary 1. **Microbiome -** Microbiomic characterisation pre and post stent intervention – as assessed by bacterial DNA analysis 2. **Motility -** MR assessed small bowel motility pre and post stent intervention 3. **Metabolomic -** Metabolomic impact pre and post stent intervention – as assessed by Gas Chromatography (GS) 4. **Clinical -** Clinical impact of Self Expanding Metal Stents (SEMS) intervention on Crohn's ileocolonic strictures. i. Paired assessment with validated IBD Scoring Tools (CDAI, HBI, IBD-Q) Secondary 1. **Recruitment rate / Standardised IBD Assessments**
Statistical methods	The primary aim of this pilot study is to produce descriptive data regarding endpoints. All endpoints related to observations completed on a pre/post basis. Given a repeated-measure study design paired sample t-tests (or the non-parametric paired test, Wilcoxon signed rank test) will be performed, evaluating pre-post changes in results.