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Daily consumers of drip-filtered coffee have a decreased risk of developing late-onset Crohn's disease

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Background: Coffee is known to impact on colon motility, alter gut-related immune response, and to affect symptoms among inflammatory bowel disease (IBD) patients. In spite of this, the role of coffee as a determinant of IBD is unclear. The aim of this study was to investigate how coffee correlates to the risk of developing late-onset IBD in general, and subdivided into Crohn's disease and ulcerative colitis.
Methods: This nested case-control study within the large, population-based Northern Sweden Health and Disease Study (NSHDS), included data from 78 patients with IBD and 311 controls matched for age, sex, time and area of sample collection. Cases were included in NSHDS at least one year prior to IBD diagnosis. Coffee consumption was assessed by questionnaire-data, differing between drip-filtered and boiled unfiltered coffee. Risk associations were estimated through conditional logistic regressions.
Results: Results differed between different subgroups of IBD and coffee. Our main finding was a decreased risk of Crohn's disease in subjects with a daily intake of drip-filtered coffee in comparison with subjects with a less frequent intake (Table). After adjustments for smoking, body-mass-index, educational level and marital status the results remained. Adjusted OR for Crohn's disease was 0.22; 95% CI 0.07–0.76

UC 56 cases, 223 controls	>1 vs. 0–1 times per day; OR (95% CI)	*p*-value
Total coffee groups	0.79 (0.38–1.62)	0.52
Drip-filtered coffee groups	1.22 (0.67–2.22)	0.52
Boiled coffee groups	1.11 (0.55–2.26)	0.77
CD 22 cases, 88 controls		
Total coffee groups	0.31 (0.09–1.07)	0.063
Drip-filtered coffee groups	0.27 (0.10–0.76)	0.013
Boiled coffee groups	1.56 (0.44–5.50)	0.49

Conclusion: Our results indicate potential biochemical differences depending on coffee preparation technique on IBD risk, with possible implications for prevention or treatment. Further studies are warranted.

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A randomised, placebo-controlled pilot trial of faecal microbiota transplantation for paediatric Crohn's disease

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Background: The role of faecal microbiota transplant (FMT) in Crohn's disease (CD) remains unclear. Small, open-label case series have shown high rates of clinical remission but protocols have varied across studies, and no randomised controlled trials (RCT) have been performed. We present a protocol for the first pilot RCT of FMT in paediatric CD patients, using a novel colonoscopic + oral capsular intervention that uses fresh-frozen and prepared, lyophilised donor stool. We will measure improvements in clinical disease activity, inflammatory biomarkers, endoscopic markers of mucosal inflammation, as well as, assess key aspects of trial feasibility.
Methods: Patients 3–17 years with active CD, on stable medication doses for 4 weeks are eligible. Patients will have an initial colonoscopy during which they will receive an infusion into the terminal ileum of normal saline (placebo) or prepared healthy donor stool (RBX2660; Rebiotix, USA) (active). This will be followed by 6-weeks of bi-weekly oral capsular therapy, containing methylcellulose (placebo) or lyophilised healthy adult donor stool (RBX7455; Rebiotix, USA). Randomisation is 2:1 to active and placebo arms (n = 45). Patients will be followed over 24 weeks. (Figure 1)
Results: Study feasibility will be assessed by: rate of recruitment, completion of sample collections, and frequency and type of adverse events. Clinical outcomes will be measured serially using: Paediatric Crohn's Disease Activity Index (PCDAI), faecal calprotectin, blood inflammatory markers, and Simple Endoscopic Score for Crohn's Disease (SES-CD) at baseline and end-of-study. Stool 16s rRNA, metagenomics, and urine metabolomics profiles will be performed on collected stool and urine samples. Patients who complete the placebo arm will be eligible to enter an open-label extension study.
Results will be measured through ITT and PP analyses. Proportions and percentages will be reported on feasibility outcomes; odds ratios, mean differences and 95% confidence intervals will be reported on clinical outcomes as preliminary estimates of efficacy.
Conclusion: This is the first pilot RCT of FMT in the treatment of CD. Recruitment commenced April 2019 and 13 patients have met screening criteria, with 5 enrolled thus far. This study is novel for its focus on paediatric CD patients, and its use of a combined oral + colonoscopic FMT delivery method. The results of this trial will offer preliminary estimates of efficacy for FMT-based therapies in CD, and may support expansion to a future larger multicenter paediatric RCT using our validated study protocol.

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Ulcerative colitis drug development success rates are higher than the industry average

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