



Inflammation, Microbiome & Alimentation  Gastro-Intestinal & Neuropsychiatric Effects

FECAL TRANSPLANT SUB-STUDIES

DR. PAUL MOAYYEDI



Strategy for Patient-Oriented Research

SPOR

Putting Patients First 

IMAGINE | FMT in Ulcerative Colitis

- Research Team:
 - PI: Paul Moayyedi (McMaster University)
- Study Purpose/Design:
 - Randomized controlled trial of FMT with pre-antibiotic treatment vs. placebo for the induction of remission in UC patients
- Update:
 - Recruitment complete
 - Analysis underway



Inflammation, Microbiome & Alimentation: Gastro-Intestinal & Neuropsychiatric Effects



IMAGINE | FMT for Crohn's disease

- Research Team:
 - Edmonton: D Kao/K Wong/K Madsen
 - Hamilton: P Moayyedi et al
 - Calgary: H Jijon et al
- Study Purpose/Goal: to determine efficacy and safety of FMT in mild to moderate Crohn's disease
- Study Design: RCT
 - FMT vs water
 - 1:1
 - Stratified by disease duration (1 yr) and biologic (Y/N)
 - Open label extension (12 weeks)
 - 1st FMT by colonoscopy (SES-CD #1), followed by weekly capsules (20) x 7 weeks
 - Repeat colonoscopy at week 8 (SES-CD #2)



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects



Strategy for Patient-Oriented Research

SPOR

Putting Patients First

IMAGINE | FMT for Crohn's disease

- **Subject Eligibility:**
- **Key inclusion criteria:**
 - Age ≥ 18
 - Diagnosis of ileo-colonic or colonic CD prior to enrollment by endoscopic evidence and confirmed by histopathology
 - Modified Harvey Bradshaw Index (HBI) score > 5
 - Evidence of active colonic inflammation with at least one of the following: elevated CRP level ≥ 8 mg/L, or elevated fecal calprotectin level ≥ 250 ug/g
- **Key exclusion criteria**
 - Active perianal disease
 - Any conditions requiring concurrent antibiotic therapy
 - Extensive colonic resection, subtotal or total colectomy
- **Recruitment Target:**
 - 126



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects



Strategy for Patient-Oriented Research

SPOR

Putting Patients First

IMAGINE | FMT for Crohn's disease

- **Progress to Date:**
 - REB Approval: yes
 - Active Recruitment Sites: 3
 - But on hold due to COVID
 - Edmonton has resumed since late summer 2020
 - Subjects screened/enrolled:
 - Edmonton
 - 11 completed study
 - 1 active participant (enrolled after COVID)
 - Hamilton
 - 11 completed study
 - On hold due to COVID
 - Calgary
 - 8 completed study
 - On hold due to COVID
- **Challenges to Date**
 - COVID-19 in 2020
 - Many patients with endoscopic disease do not have enough symptoms
- **Plans to mitigate challenges**
 - Calgary is resuming research activity soon



Inflammation, Microbiome & Alimentation
Gastro-Intestinal & Neuropsychiatric Effects



IMAGINE | FMT in Pouchitis

- Research Team:

- PI: Neeraj Narula (McMaster University)
- Co-Investigators: Paul Moayyedi, John Marshall, Geoff Nguyen, Vipul Jairath, Dina Kao, Karen Wong

- Study Purpose/Design:

- Randomized controlled trial of FMT vs. placebo for the induction of remission in patients with active pouchitis

- Update:

- 14 out of 50 patients recruited
- study was on hold to new recruitments from March-October due to COVID-19 and issues with using stool that has not been screened for SARS-CoV
- contracting underway with University of Manitoba and Ottawa as additional study sites



Inflammation, Microbiome & Alimentation: Gastro-Intestinal & Neuropsychiatric Effects



IMAGINE | FMT in IBS with Depression

- Research Team:
 - PI: Valerie Taylor (University of Calgary)
- Study Purpose/Design:
 - Randomized controlled trial of FMT vs. Placebo in patients with IBS & major depressive disorder
- Update:
 - FMT protocol approved by Health Canada
 - REB approval
 - Recruitment delays due to new Health Canada guidelines & COVID-19



Inflammation, Microbiome & Alimentation: Gastro-Intestinal & Neuropsychiatric Effects

