Fecal Microbiota Transplantation for Active Pouchitis: A Randomized Controlled Trial

Inclusion Criteria

- Patients aged 18 or over
- Active pouchitis defined as PDAI of 7-18 points, with endoscopic subscore at > 2
- Females of child bearing potential must be willing and able to use acceptable contraception as per Appendix III. II. b. Toxicity section of the Health Canada Guidance

Exclusion Criteria

- Participating in another clinical trial
- Unable to give informed consent
- Severe comorbid medical illness
- Concomitant Clostridium difficile infection
- Increase in medical therapy for pouchitis in the last 4 weeks. Continued treatment with 5-ASA, azathioprine, 6-mercaptopurine or anti-TNFa therapy (e.g. infliximab) will be permitted if taken at stable dose for ≥8 weeks prior to randomization. Stable dose (same dose for at least 2 weeks) or a tapering dose of steroids will also be permitted provided the dose of steroid is not increased again. Stable intake of probiotic therapy also permitted.
- New antibiotic therapy in the last 28 days.
- Pregnant women.
- Clinically significant lactose intolerance
- Any condition, in the opinion of the investigator, that the treatment may pose a health risk to the subject, based on lab study results