



# Evaluation of an oral microbiota-based therapeutic as a treatment option for primary sclerosing cholangitis

Status: Recruiting

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# Eligibility Criteria

Sex: Male or Female Age Group: 18 years and over This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

- ages 18-76 - serum total bilirubin  $\leq$  2x the upper limit of normal - expect to maintain current medication regimen for the duration of the study - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

#### **Exclusion Criteria:**

- received antibiotic therapy (except vancomycin) in the past 3 months - complications of advanced PSC, such as hepatic encephalopathy, ascites, history of esophageal varices, portal hypertension, hepato-renal syndrome, portopulmonary syndrome, and hepato-pulmonary syndrome - viral hepatitis (history of Hepatitis C is eligible with undetectable HCV RNA); HIV/AIDS - liver disease such as metabolic or inherited disease or cirrhosis - women who are pregnant, breast feeding, or trying to become pregnant -active cancer - active alcohol overuse (>4 drinks per day for men, and >2 drinks per day for women)

### **Conditions & Interventions**

Conditions: Digestive & Liver Health, Microbiota Keywords: Clinics and Surgery Center (CSC), Primary Sclerosing Cholangitis, PSC

## More Information

Description: We are studying the safety and feasibility of microbiota transplant therapy (MTT) for patients with Primary Sclerosing Cholangitis (PSC). The purpose of this study is to evaluate whether MTT from a healthy donor is safe and can be used to restore the healthy composition of microbiota to help decrease disease severity and improve symptoms. All patients in this study will receive capsules of the drug, MTT. Study Contact: Amanda Kabage - kaba0012@umn.edu Principal Investigator: Elizabeth Aby Phase: EARLY\_PHASE1 IRB Number: STUDY00020840

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