Determine the Prevalence of Exocrine Pancreatic Insufficiency (EPI) in Pediatric and Adult Participants With Alagille Syndrome After Liver Transplantation

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 7 years to 50 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Male and female participants ages 7-50 years inclusive.
- Confirmed diagnosis of ALGS
- Status post OLT due to ALGS complications.
- Participants currently managed with pancreatic enzyme products (PEPs) are allowed pending discontinuation of PEPs for 5 days prior to beginning the 72-hour stool collections. Participants must discontinue PEPs for the entire study period until completion.
- Agree to adhere to a high fat diet at least 2 days prior to and during the 72-hour stool collections and monitor dietary consumption through the use of a diet diary.
- Have a consistent caregiver for the duration of the study if applicable for enrollment of a child.
- Capable of giving written informed consent and assent (if age appropriate).

Exclusion Criteria:

- Surgical disruption of the enterohepatic circulation (e.g., biliary diversion).
- Subjects with alternative etiologies of EPI (e.g., chronic panreatitis, pancreatic resection).
- Diets high in medium-chain triglyceride (MCT) oil.
- Use of bile acids, bile acid uptake inhibitors, lipid-binding resins, synthetic fat substitutes (e.g. Olestra), and diaper rash ointments (note that H2 antagonists and proton pump inhibitors [PPIs] are permitted if on a stable and consistent regimen throughout the duration of the study).
- History or presence of other concomitant liver diseases such as liver transplant rejection with cholestasis, hepatitis B or C virus infection, HIV, primary sclerosing cholangitis (PSC), alcoholic liver disease, autoimmune hepatitis, metabolic-associated fatty liver disease (MASLD)/non-alcoholic steatohepatitis (NASH) or significant chronic allograft rejection.
- Currently pregnant or breastfeeding.
- Cancers except for in situ carcinoma or cancers treated at least 5 years prior to screening with no evidence of recurrence.
- Participation in a clinical trial and received an investigational product within the last 30 days.
- Use of anti-diarrheal, anti-spasmodic, and/or cathartic laxatives. Change in osmotic laxatives within the past 3 months.

Conditions & Interventions

Interventions:
DIAGNOSTIC_TEST: Fecal Fat
Conditions:
Exocrine Pancreatic Insuficiency
Keywords:
Alagille Syndrome, steatorrhea, liver transplant, fecal fat, coefficient of fat, exocrine pancreatic insufficiency

More Information

Description:
The goal of this clinical trial is to determine the prevalence of exocrine pancreatic insufficiency (EPI) in a population of pediatric and adult participants with Alagille Syndrome (ALGS) post liver transplant. During the study, participants will: * Consume a high fat diet * Keep a diary of their abdominal signs and symptoms, and stool frequency and consistency * Collect stool for laboratory testing

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