Liver Cirrhosis Network Cohort Study

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Age ≥ 18 years * Willing to provide samples at baseline * Cirrhosis Where Cirrhosis is defined as: 1. At least one liver biopsy within 5 years prior to consent showing either: a) Metavir stage 4 fibrosis; Ishak Stage 5-6 fibrosis OR 2. At least 2 of the following: 1. Evidence on imaging: Nodular liver with either splenomegaly or recanalized umbilical vein within the past year 2. Liver stiffness: VCTE within one year prior to consent or during Screening ≥12.5 kPa or MRE within one year prior to consent or during Screening ≥5 kPa 3. Evidence of varices demonstrated on imaging or endoscopy within 3 years prior to consent or during Screening 4. Either: FIB-4\>2.67 or platelets \<150/mL within 6 months prior to consent or during Screening 5. \>5 years METAVIR stage 4 fibrosis or Ishak stage 5-6

Exclusion Criteria:

* Known and documented prior or current hepatocellular carcinoma (HCC) or cholangiocarcinoma * Known transjugular intrahepatic portosystemic shunt (TIPS), balloon retrograde transvenous obliteration (BRTO) or porto-systemic shunt surgery regardless of time of occurrence * Known prior solid organ transplant or bone marrow transplant * Current participation in active medication treatment trials at the time of consent for LCN Cohort Study * Prisoners or individuals with more than 180 days incarceration pending due to difficulty with visits * Bariatric surgery in the last 180 days prior to consent * Known history of fontan procedure-associated liver disease (FALD) * Known current medical or psychiatric conditions which, in the opinion of the investigator, would make the participant unsuitable for the study or interfere with or prevent follow-up per protocol * Current liver-unrelated end-stage organ failures (Dialysis, stage 3-4 congestive heart failure (CHF), current chronic obstructive pulmonary disease (COPD) on home oxygen, current known active malignancy besides non-melanomatous skin cancer or carcinoma in situ) * Documented history of acute alcohol-associated hepatitis (according to NIAAA criteria as described in the MOP) in the 180 days prior to consent * Documented current or continued signs and symptoms of acute Wilson disease (acute liver failure, acute neurological deficits, hemolysis) * In patients with primary sclerosing cholangitis (PSC): Current active cholangitis with 90 days prior to consent * Documented cardiac cirrhosis * Known recent (within the last 365 days) or present hepatic decompensation with ascites/hydrothorax (including trace ascites discovered at screening not requiring intervention), hepatic encephalopathy or variceal bleeding. If a patient has had a history of decompensation, they must have been off any medications to treat decompensation for at least 365 days. Refer to the MOP for clarifying details on evaluating eligibility for patients with a history of prior decompensation. * Known or documented habitual non-adherence to previous research studies or medical procedures or unwillingness to adhere to protocol (e.g., unwilling to obtain consent or samples) * Current model for end-stage liver disease (MELD-Na) cut off ≥ 15* * Current Child-Turcotte-Pugh (CTP) B or C* * Current known Hepatitis C Virus (HCV) without sustained virologic response (SVR) * Current known quantifiable Hepatitis B Virus (HBV) viral DNA on therapy with ongoing adherence on suppressive therapy* * In patients with autoimmune hepatitis: serum aspartate aminotransferase (AST) \> 2X upper limit of normal (ULN) within 90 days prior to consent or during Screening* * In patients living with HIV: CD4+ T cell count less than 100 cells/mm3 within 90 days prior to consent or during Screening* * Indicates an exclusion criterion that may depend on laboratory results and other clinical assessments to be ordered during Screening after confirming the participant is otherwise eligible. If the test was performed as standard-of-care in the 90 days prior to consent, it does not need to be re-done for eligibility.

Conditions & Interventions

Conditions:
Cirrhosis, Cirrhosis, Liver, Cirrhosis Early, Cirrhosis Due to Hepatitis B, Cirrhosis Advanced, Cirrhosis Infectious, Cirrhosis Alcoholic, Cirrhosis, Biliary, Cirrhosis Cryptogenic, Cirrhosis Due to Hepatitis C, Cirrhosis Due to Primary Sclerosing Cholangitis, Autoimmune Hepatitis

Keywords:
Cirrhosis, Liver, Nonalcoholic Fatty Liver Disease, NASH, Nonalcoholic steatohepatitis

More Information

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