

Global Prospective, Observational Cohort of Adult Patients With Primary Sclerosing Cholangitis (WIND-PSC Study)

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Adult patients between 18 and 75 years of age (inclusive) who can comprehend instructions, follow the study procedures and are willing to sign an Informed Consent Form (ICF). 2. Confirmed clinical diagnosis of large duct PSC based on current AASLD Guidelines (Bowlus 2023).

Exclusion Criteria:

1. Clinically significant acute or chronic liver disease of an etiology other than PSC (with or without presence of features of AIH). 2. Small-Duct PSC. 3. Clinically diagnosed secondary or IgG4-related sclerosing cholangitis. 4. Clinically diagnosed acute cholangitis and currently receiving treatment. Patients on chronic suppressive antibiotics will be allowed to enroll. 5. UDCA dose ≥ 28 mg/kg. 6. Evidence of current or historical decompensated cirrhosis based on the following clinical events: * Ascites \geq Grade 2 and requiring treatment * Esophageal or gastric variceal bleeding requiring hospitalization * Hepatic encephalopathy (as defined by a West Haven score ≥ 2) * Spontaneous bacterial peritonitis defined as ascites absolute neutrophil count $\geq 250/\text{mm}^3$ in the absence of an intra-abdominal source of infection * AKI-HRS according to AASLD Guidelines (Flamm 2021). 7. Prior liver transplantation. 8. MELD-Na Score ≥ 15 . For subjects on anticoagulation medication, baseline INR determination for MELD score calculation should take this use into account. 9. Participants with current clinical or laboratory evidence of any severe, progressive, or uncontrolled disease, related or unrelated to PSC and which, in the opinion of the investigator, has an expected survival of less than 48 weeks. 10. Participants who are impaired, incapacitated, or incapable of completing study-related assessments or giving informed consent. 11. Prisoners or participants who are involuntarily incarcerated. 12. Participants who are currently participating in an interventional clinical study. 13. Absence of data in medical records to assess inclusion and exclusion criteria.

Conditions & Interventions

Conditions:

PSC

More Information

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Principal Investigator:

Phase:

IRB

Number:

System ID: NCT06297993

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