

Biochemical Response and Clinical Outcomes in Patients With PBC

NCT07449793

Status RECRUITING
Sponsor RenJi Hospital
Enrollment 3,000 participants

Key Eligibility Criteria

Inclusion (3)

- Age above 18 years old, Male or Female,
- Diagnosis of PBC meeting the 2018 American Association for the Study of Liver Diseases (AASLD) Practice Guidelines criteria;
- Treatment with UDCA at a standard dose (13-15 mg/kg/day), with or without other second-line medications.

Exclusion (5)

- Co-existing liver diseases, including but not limited to: Hepatitis C virus infection; Active Hepatitis B infection (patients who are HBsAg-negative and HBeAg-negative may be considered eligible per investigator assessment);
- Autoimmune Hepatitis (AIH); Primary Sclerosing Cholangitis (PSC); Suspected or confirmed hepatocellular carcinoma;
- Female subjects who is pregnant or breastfeeding during the study;
- History of other malignancies, including hematological tumors, solid tumors except hepatobiliary system;
- Poor adherence or inability to complete the study follow-up.

Locations (1 total)

RenJi Hospital, Shanghai, Shanghai Municipality, China