

Fenofibrate Combined With Ursodeoxycholic Acid in Subjects With Primary Biliary Cholangitis

NCT05751967

Status	RECRUITING
Phase	Phase 3
Sponsor	Xijing Hospital of Digestive Diseases
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (8)

- Must have provided written informed consent;
- Age 18-75 years;
- BMI 17-28 kg/m²
- Male or female with a diagnosis of PBC, by at least two of the following criteria:
- History of AP above ULN for at least six months;
- ... and 3 more (see full listing online)

Exclusion (12)

- History or presence of other concomitant liver diseases.
- ALT/AST \gt 5xULN, TBIL \gt 3xULN.
- If female: known pregnancy, or has a positive urine pregnancy test (confirmed by a positive serum pregnancy test), or lactating.
- Allergic to fenofibrate or ursodeoxycholic acid.
- Taking hepatotoxic drugs (e.g., dapsone, erythromycin, fluconazole, ketoconazole, rifampicin) for more than 2 weeks within 6 months, and long-term hormonal users.
- ... and 7 more (see full listing online)

Locations (7 total)

The second hospital of Lanzhou University, Lanzhou, Gansu, China
Sun Yat-sen Memorial Hospital, Guangzhou, Guangdong, China
Nanjing Drum Tower Hospital, Nanjing, Jiangsu, China
... and 4 more locations