

Fenofibrate in Primary Biliary Cholangitis: a Real World Study

NCT06755151

Status	RECRUITING
Phase	Phase 3
Sponsor	Xijing Hospital of Digestive Diseases
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (4)

- Must have given written informed consent (signed and dated)
- Completed in a PBC study with fenofibrate(NCT05749822,NCT06174402)
- ALP $> 1 \times$ ULN
- Females of reproductive potential must use at least one barrier contraceptive and a second effective birth control method during the study and for at least 90 days after the last dose. Male subjects who are sexually active with female partners of reproductive potential must use barrier contraception and their female partners must use a second effective birth control method during the study and for at least 90 days after the last dose

Exclusion (2)

- Treatment-related adverse event (AE) leading to study drug discontinuation in a previous PBC study with seladelpar
- A medical condition, other than PBC, that in the Investigator's opinion would preclude full participation in the study or confound its results

Locations (1 total)

Xijing hospital, Xi'an, Shaanxi, China