# Fenofibrate in Patients With Primary Biliary Cholangitis (PBC)

NCT06365424

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| **Status** | RECRUITING |
| **Phase** | Phase 2, Phase 3 |
| **Sponsor** | Xijing Hospital of Digestive Diseases |
| **Enrollment** | 117 participants |

## Plain Language Summary

This study is a long-term follow-up for patients who previously participated in a clinical trial of fenofibrate (a medication typically used for cholesterol) as a treatment for primary biliary cholangitis (PBC) — a chronic liver disease where the immune system attacks the bile ducts.

**You may be eligible if...**
- You previously participated in the fenofibrate PBC clinical trial (NCT02823353)
- You are using appropriate contraception if you are of reproductive potential

**You may NOT be eligible if...**
- You had to stop taking fenofibrate in the previous trial due to a treatment-related side effect
- You have another medical condition that your doctor believes would prevent you from safely completing this study

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

### Inclusion (3)

- Must have given written informed consent (signed and dated)
- Participated in the PBC study with fenofibrate (NCT02823353)
- 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 (6)

- Treatment-related adverse event (AE) leading to fenofibrate discontinuation
- A medical condition, other than PBC, that in the investigator's opinion would preclude full participation in the study or confound its results (e.g., cancer)
- Known history of other liver diseases
- For females, pregnancy or breast-feeding
- Long-term use of immunosuppressive agents

... and 1 more (see full listing online)

## Locations (1 total)

Xijing Hospital, Xi'an, Shaanxi, China