FIREFLY Trial: Fenofibrate Intervention---Randomized Evaluation in First-Line PBC Therapy

NCT07296458

Status	RECRUITING
Phase	Phase 3
Sponsor	Xijing Hospital of Digestive Diseases
Enrollment	132 participants

Key Eligibility Criteria

Inclusion (4)

- Voluntarily join the group and be able to understand and sign the informed consent form;
- Age: 18 years old or above and below 75 years old;
- The diagnosis of primary biliary cholangitis follows the AASLD international diagnostic and treatment guidelines (meeting two of the following three criteria: positive AMA or gp210, sp100; elevated serum ALP; pathological manifestations of non-suppurative cholangitis and interlobular bile duct destruction);
- The patient did not receive UDCA and fenofibrate treatment in the 6 months before enrollment, and ALP was greater than the upper limit of normal (ULN).

Exclusion (16)

- Combined liver diseases caused by other factors: including viral hepatitis, chronic alcoholic hepatitis, steatohepatitis, drug-induced hepatitis, autoimmune hepatitis, primary sclerosing cholangitis, etc;
- Pregnant women, lactating women, or those who plan to give birth during the study period;
- Individuals who are allergic to fenofibrate or ursodeoxycholic acid;
- At the time of diagnosis or in the past, there have been variceal bleeding, hepatic encephalopathy, ascites, spontaneous bacterial peritonitis, hepatocellular carcinoma, and hepatorenal syndrome;
- Individuals with a history of severe diseases or functional failures in the heart, cerebrovascular system, kidneys, respiratory system, as well as mental illnesses (including those caused by alcohol and drug abuse);

... and 11 more (see full listing online)

Locations (1 total)

Xijing Hospital, Xi'an, Shaanxi, China