A Clinical Study to Evaluate the Safety and Efficacy of LY-M003 Injection in Patients With Wilson Disease

NCT06650319

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Chaohui Yu
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (8)

- The subject must be able to fully understood the purpose, nature, method, and possible adverse effects of the study, must be able to voluntarily participate in the study and voluntarily able to provide the written informed consent form (ICF).
- Patients diagnosed with Wilson Disease .
- Wilson Disease (WD) patients confirmed by laboratory tests to have biallelic mutations in the ATP7B gene.
- Subjects must be treatment-experienced to WD who have received standard treatment (eg, D-penicillamine or zinc acetate) for at least 6 months prior to the screening period.
- Subjects must restrict food with high copper content for at least 6 months prior to screening and continue this restriction during the entire duration of study participation.

... and 3 more (see full listing online)

Exclusion (26)

- AAV8 neutralizing antibody titer \> 1:10 .
- Active gastrointestinal bleeding within the past 3 months.
- Decompensated cirrhosis or advanced hepatic disease, manifested as portal hypertension, ascites, splenomegaly, esophageal varices, hepatic encephalopathy, etc.
- Subjects with other liver diseases as determined by the investigator, such as immune hepatitis, alcoholic liver disease, primary biliary cholangitis, primary sclerosing cholangitis, and/or drug or toxic liver disease
- Subjects considered as complicated with severe hypersplenism and requiring splenectomy as judged by the investigator.

... and 21 more (see full listing online)

Locations (1 total)

First Affiliated Hospital of Zhejiang University, Hangzhou, Zhejiang, China