Trial of CS060380 Tablets for Non-alcoholic Steatohepatitis (NASH)

NCT07198386

Status	RECRUITING
Phase	Phase 2
Sponsor	Cascade Pharmaceuticals, Inc
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (8)

- Men or women aged 18 to 70 (including the boundary value).
- Liver biopsy results within 6 months prior to randomization were consistent with the pathological diagnosis of NASH, and the non-alcoholic fatty liver disease activity score (NAS) was e4 points, with at least 1 point each for inflammation and balloon changes, and the fibrosis stage of the Clinical Study Network for Non-alcoholic Steatohepatitis (NASH-CRN) in the United States was F1-F3; Or, the liver fat content is confirmed to be e 10% based on the magnetic MRI-PDFF results of this hospital within the previous 3 months..
- Participants with fertility and their spouses or partners voluntarily took effective contraceptive measures from screening to within 3 months after the last administration. Among them, women of childbearing age include premenopausal women and women within two years after menopause, except those who have undergone hysterectomy or bilateral oophorectomy or have medically confirmed ovarian failure.
- Before randomization, there were stable ALT and AST results. If the ALT or AST value during the screening period was e 1.5 × (ULN), it is necessary to have continuous 2 stable evidences before randomization (the two evaluations need to be spaced at least 2 weeks apart), and one of the following evidences must be met:
- Compared with the historical data within 2 weeks to 3 months before the screening process (if any, and the value d5×ULN), the ALT or AST value during the screening period needs to increase by d30% compared with the historical data.

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

Exclusion (48)

- The following liver diseases or past medical history were present at the time of screening:
- Patients with other clinically significant acute or chronic liver diseases or biliary tract diseases not caused by NASH, and the researchers determined that not suitable to participate in this study, Including but not limited to hepatitis B virus, Untreated hepatitis C virus, DILI, ALD, WD, AIH, PBC, PSC.
- Has a history of liver cirrhosis.
- Primary liver cancer. AFP \> 50 ɡ/L.
- During screening, the following medical history was present:

... and 43 more (see full listing online)

Locations (8 total)

The First Affiliated Hospital of Fujian Medical University, Fuzhou, Fujian, China
Xiamen Hospital of T.C,M., Xiamen, Fujian, China
The Fifth People's Hospital of Suzhou, Suzhou, Jiangsu, China
... and 5 more locations