

A Randomized, Double-blind, Placebo-controlled, First-in-human, 3-Part Study of Orally Administered ALS-002158 to Evaluate the Safety, Tolerability and Pharmacokinetics of Single Ascending Dosing and Food-effect in Healthy Volunteers, and Multiple Ascending Dosing in Subjects with Chronic Hepatitis C Genotype 1 Infection.

ACTRN12612000176864

Status	RECRUITING
Phase	Phase 1
Sponsor	CPR Pharma Services
Enrollment	78 participants

Key Eligibility Criteria

Inclusion (28)

- Subjects must meet all of the following criteria to be included in the study:
 - Subject has provided written consent.
 - In the investigator's opinion, the subject is able to understand and comply with protocol requirements, instructions, and protocol.
 - Subject is in good health as deemed by the investigator, based on the findings of a medical evaluation including medical history, physical examination, laboratory tests,
 - and ECG.
- ... and 23 more (see full listing online)

Exclusion (27)

- Subjects will be ineligible for this study if they meet any one of the following criteria:
 - Clinically significant cardiovascular, respiratory, renal, gastrointestinal, hematologic, neurologic, thyroid, or any uncontrolled medical illness or psychiatric disorder.
 - Positive test for HAV IgM, HBsAg, HCV Ab (HV only), or HIV Ab.
 - Abnormal screening laboratory results that are considered clinically significant by the investigator.
 - Liver function tests must all be within normal ranges for healthy volunteers (subjects with documented Gilbert's disease allowed).
- ... and 22 more (see full listing online)

Locations (4 total)

New Zealand
Romania
France
... and 1 more locations