Phase 1 Open-Label Study of Radiprodil Pharmacokinetics, Safety, and Tolerability in Hepatically Impaired Participants

NCT07457229

Status	RECRUITING
Phase	Phase 1
Sponsor	GRIN Therapeutics, Inc.
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (7)

- Male or female participants aged 18 to 75 years, inclusive, at Screening.
- Body mass index (BMI) within the range specified in the protocol.
- Participants with hepatic impairment must have stable mild (Child-Pugh Class A), moderate (Child-Pugh Class B), or severe (Child-Pugh Class C) hepatic impairment, as applicable to cohort assignment.
- Healthy participants must be medically healthy with no clinically significant abnormalities as determined by the investigator.
- Participants must be willing and able to comply with all study procedures and confinement requirements.

... and 2 more (see full listing online)

Exclusion (8)

- History or presence of clinically significant medical conditions that could interfere with study participation or interpretation of results.
- Positive test for drugs of abuse, alcohol, or cotinine (where applicable) at Screening or check-in.
- Positive serology for HIV, hepatitis B surface antigen, or hepatitis C virus.
- Clinically significant abnormal laboratory values, vital signs, or ECG findings at Screening or Day -1, as judged by the investigator.
- Use of prohibited concomitant medications or substances that may interfere with radiprodil metabolism.

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

Locations (2 total)

Epic Medical Research, DeSoto, Texas, United States
Texas Liver Institute, San Antonio, Texas, United States