SAMe Trial for Patients With Alcoholic Cirrhosis

NCT04250259

Status	RECRUITING
Phase	Phase 2
Sponsor	Indiana University
Enrollment	196 participants

Key Eligibility Criteria

Inclusion (4)

- Evidence of cirrhosis as per clinical signs and/or noninvasive transient elastography (Fibroscan®), computed tomography, magnetic resonance imaging including MRI elastography compatible with cirrhosis and/or histopathology by biopsy and
- subjects with clinical presentation either in Child Class A or B at the time of enrollment
- individuals 18 to 70 years old and may or may not consume alcohol during study.
-) individuals 18 to 70 years old (2) able to provide informed consent (3) subjects do not consume any alcohol or those who drink \< 50 grams per day on average in women and \< 80 grams per day on average in men (4) subjects are healthy without underlying acute or chronic medical conditions.

Exclusion (15)

- Active infection as evidenced by positive urine culture, blood culture, or pneumonia,
- Known co-existing infection with hepatitis C, hepatitis B, or HIV
- Significant systemic or major illness including chronic obstructive pulmonary disease, congestive heart failure, and renal failure that in the opinion of the Investigator would preclude the patient from participating in and completing the study
- Gastrointestinal bleeding within the prior 28 days3
- Participation in another investigational drug, biologic, or medical device trial within 30 days prior to screening

... and 10 more (see full listing online)

Locations (2 total)

Cedars-Sinai Medical Center, Los Angeles, California, United States
Indiana University Hospital, Indianapolis, Indiana, United States

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.