

Study to Evaluate the Safety and Efficacy of Larsucoesterol in Participants With Alcohol-associated Hepatitis (AH)

NCT07428538

Status	RECRUITING
Phase	Phase 3
Sponsor	Bausch Health Americas, Inc.
Enrollment	350 participants

Key Eligibility Criteria

Inclusion (19)

- A participant will be eligible for inclusion in this study if he/she meets all the following criteria:
 - Able to provide written informed consent (either from participant or participant's legally acceptable representative).
 - Onset of jaundice within 8 weeks before hospital admission.
 - Average daily consumption of greater than (>) 40 (females) or >60 (males) grams alcohol for 6 months or longer, with less than (<) 8 weeks of abstinence before the onset of jaundice. Judgment regarding daily and long-term alcohol use and onset of jaundice will be made and documented by the site Investigator.
 - The determination of AH will be based on typical serum chemistry (as determined by local laboratory):
- ... and 14 more (see full listing online)

Exclusion (42)

- A participant will be excluded from the study if he or she meets any of the following criteria:
 - Participants using systemic corticosteroids for current AH before enrollment or having a history of using systemic corticosteroids for more than 8 days in the last 30 days prior to screening.
 - NOTE: Inhaled, topical, or local corticosteroid injections are permitted NOTE: A participant who has a confirmed diagnosis of hypoadrenalism and is taking a physiological replacement dose of hydrocortisone (or equivalent) is permitted to take part in the trial
 - Participants experiencing or considered at high risk for alcohol withdrawal seizures or delirium tremens.
 - Active infection (such as spontaneous bacterial peritonitis [SBP], urinary tract infection [UTI], cellulitis, pneumonia, bacteremia, acute viral hepatitis, uncontrolled HIV, and active SARS CoV2 infection).
- ... and 37 more (see full listing online)

Locations (48 total)

University of Alabama at Birmingham (UAB) Hospital, Birmingham, Alabama, United States
Banner - University Medical Center, Phoenix, Arizona, Phoenix, Arizona, United States
Mayo Clinic - Phoenix, Phoenix, Arizona, United States
... and 45 more locations