

Treatment for Immune Mediated Pathophysiology

NCT04862221

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Enrollment	163 participants

Key Eligibility Criteria

Inclusion (4)

- Patient with liver injury of ≥ 6 weeks duration resulting in an international normalization ratio (INR) of ≥ 1.5 or < 2.0 (not corrected by vitamin K) with evidence of hepatic encephalopathy (HE), INR of ≥ 1.5 or < 2.0 for at least 7 days duration without evidence of HE or INR ≥ 2.0 without evidence of HE.
- Age is greater than or equal to 1 year and less than 18 years of age.
- Patient or their legally authorized representative(s) (LAR) must consent (and assent, if applicable) to be in the study and must have signed and dated an approved informed consent form which conforms to federal and institutional guidelines.
- Females of reproductive potential should not plan on conceiving children during the study and must agree to use a medically accepted form of contraception.

Exclusion (24)

- Evidence of active infection with Hepatitis A, B, C, E or evidence of acute herpes simplex virus (HSV) or adenovirus infection
 - Travel within the past 3 months to an area highly endemic for Hepatitis E
 - Diagnosis of hemophagocytic lymphohistiocytosis (HLH) Note: Patients with a history of consanguinity and/or central nervous system (CNS) dysfunction that is exaggerated compared to the degree of liver dysfunction (as judged by the site investigator) will not be enrolled until results of rapid genetic testing are available. Turn-around time for genetic testing results is estimated to be 72-96 hours.
 - Aplastic anemia as defined by standardized criteria [1] diagnosed prior to enrollment
 - Diagnosis of autoimmune Hepatitis (AIH)
- ... and 19 more (see full listing online)

Locations (24 total)

Children's Hospital Los Angeles, Los Angeles, California, United States
Lucile Packard Children's Hospital, Palo Alto, California, United States
Rady Children's Hospital, San Diego, California, United States
... and 21 more locations