

miroliverELAP® for the Treatment of Acute Liver Failure: A Phase 1 Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. 18 years to 80 years old at the time of signing the informed consent 2. Subject must: 1. be deemed competent to consent by an independent qualified practitioner, or 2. have consent given by a Legally Authorized Representative 3. Subject should be in the intensive care unit 4. Be diagnosed with 4.1. Acute Liver Failure defined as: 1. INR \geq 2.0, and 2. Hepatic Encephalopathy Grade II-III (West Haven Criteria), and 3. Less than 4 weeks (28 days) of disease duration 4.2. Severe Acute Alcohol-Associated Hepatitis as defined as: 1. Hepatic Encephalopathy Grade I-III (West Haven Criteria), and 2. Model for End-Stage Liver Disease (MELD) Score \geq 20, and 3. INR \geq 2.0, and 4. No overt evidence of cirrhosis 4.3. Acute on Chronic Liver Failure: 1. Hepatic Encephalopathy Grade I-III (West Haven Criteria), and 2. Model for End-Stage Liver Disease (MELD) Score \geq 20, and 3. INR \geq 2.0, 5\ Subject is not a candidate for liver transplant and will not become a candidate in the event of worsening conditions. Exclusion Criteria 1. Grade IV West Haven Encephalopathy Criteria 2. Previous liver transplant 3. Currently requires chronic hemodialysis (CRRT or other forms of continuous renal replacement are allowed). 4. Uncontrolled documented infection, hypotension, or refractory shock. This is defined as a need for a single vasopressor, or combination of vasopressors, that exceed a norepinephrine equivalent of 0.5 mcg/kg/min. 5. Liver injury due to trauma 6. Any current liver cancer 7. Currently on medications with a narrow therapeutic index 8. Platelet count $<$ 40,000 μ L 9. If the subject is intubated and has an acute lung injury 10. Experiencing a bleeding event, defined as: 1. Active gastrointestinal or other overt bleeding event, or 2. Hemoglobin drop $>$ 3g/dL within the past 24 hours, or 3. Received \geq 3 units of red blood cell transfusion within the past 24 hours 11. Female that is currently pregnant, planning to be pregnant, or currently breastfeeding 12. Refusal to receive blood products

Conditions & Interventions

Interventions:

COMBINATION_PRODUCT: miroliverELAP treatment

Conditions:

Acute Liver Failure, Acute Liver Injury, Drug Induced, Acute on Chronic Liver Failure (ACLF), Acute Alcoholic Hepatitis

Keywords:

Acute liver failure, Extracorporeal liver assist, Bioengineered liver

More Information

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Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT06285253

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