

# The Safety ,Tolerability and Efficacy Study of HepaCure in Chinese Subjects with Acute-On-Chronic Liver Failure

NCT05989958

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Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Hexaell Biotech Co., Ltd.
Enrollment	92 participants

## Key Eligibility Criteria

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### Inclusion (4)

- Able to communicate effectively with investigators and sign the informed consent form (ICF) voluntarily.
- Age: e 18 years and d 65 years.
- Body weight: e 40kg;
- Met the criteria of ACLF in the early and middle stages in screening period (Guidelines for the Diagnosis and Treatment of Liverfailure (2018 Edition)): base on chronic liver disease, acute jaundice deepened and coagulation dysfunction caused by various inducements, manifested as extreme fatigue, with obvious gastrointestinal symptoms such as anorexia, vomiting, abdominal distention, etc; Progressive deepening of jaundice, serum TBil e 17.1 $\mu$ ol/L or increase e 17.1 $\mu$ ol/L daily or e10 x upper limit of normal value; with bleeding tendencies or manifestations (bleeding spots or ecchymosis), or 20%\<PTA d 40% (or 1.5 d INR\<2.6), and other reasons excluded.

### Exclusion (4)

- Subjects with primary or metastatic liver cancer.
- Subjects with severe esophageal/gastric varices and high risk of bleeding, with positive red signs, or with previous active bleeding, as indicated by gastroscopy or imaging examination results.
- Serum creatinine was greater than 132.6  $\mu$ ol/L.
- Subjects with serious uncontrolled infections, including sepsis, septic shock, severe pneumonia (refers to the diagnostic criteria of the American Society of Infectious Diseases/American Thoracic Society for adult severe pneumonia in 2007), abdominal infection (exist Peritonitis manifestations or white blood cells in ascites\>0.1 x 10<sup>9</sup>/L after reasonable antibiotic treatment), etc;

## Locations (1 total)

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Beijing You&#39;an Hospital affiliated to Capital Medical University, Beijing, Beijing Municipality, China