



Extracorporeal Bioengineered Dual Cell Liver Regeneration System (EBDLR-2.0)

Phase I Clinical Trials

Indian Patent No.:523925

**CDSCO approval
received for phase I
clinical trials on 3rd
October 2025**



**A multi-centre, single arm study to evaluate the safety,
tolerability and performance of**

**The Extracorporeal Bioengineered Dual-Cell Liver
Regeneration System [EBDLR System] in Acute Liver
Failure (ALF) and Acute-on-Chronic Liver Failure (ACLF)**

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INCLUSION CRITERIA

Acute-on-Chronic Liver Failure (ACLF)

- a. Age aged >18 years and <70 years both the genders.
- b. Patient or LAR/IW is able to provide informed consent voluntarily to participate in the study.
- c. Patients with known or unknown liver disease.
- d. If known: diagnosed with ACLF Grade 1, 2, or 3a, defined as per the CLIF-C OF score system.
- e. Patients with no obvious decompensation or admission to the hospital in the 30 days prior to the current visit.
- f. PT/INR ≥ 1.5 .
- g. Bilirubin > 5 mg/dL.
- h. Serum Creatinine < 2 mg/dL, with or without ascites and/or hepatic encephalopathy.
- i. Mean Arterial Pressure (MAP) > 60 mmHg (with or without inotropes)

Acute liver failure (ALF) – Acetaminophen toxicity

- a. Patients aged >18 years and <70 years both the genders.
- b. Patients or LAR /IW able to provide informed consent voluntarily to participate in the study.
- c. Patients with no previous history of liver disease/decompensation/cirrhosis.
- d. Patient diagnosed with acute liver failure due to acetaminophen overdose typical for acetaminophen toxicity.
- e. Bilirubin <10 mg/dL .
- f. Alanine aminotransferase (ALT) ≥ 1000 IU/L).
- g. PT- INR ≥ 1.5 .
- h. Serum Creatinine <1.5 mg/dL with or without ascites/encephalopathy.
- i. Mean Arterial Pressure > 60 mmHg (with or without inotropes).

Acute liver failure (ALF) – Etiologies other than acetaminophen overdose

- a. Patients aged >18 years and <70 years both.
- b. Patients or LAR /IW able to provide informed consent voluntarily to participate in the study.
- c. Patients with no previous history of liver disease /decompensation /cirrhosis.
- d. Patient diagnosed with acute liver failure of known/unknown etiology.
- e. PT- INR ≥ 1.5 .
- f. Serum Creatinine <1.5 mg/dL with or without ascites/encephalopathy.
- g. Mean arterial pressure of >60 mmHg (with or without inotropes).

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