

## BILIVER STUDY: OBSERVATIONAL STUDY on HEPATIC TOXINS KINETIC AND EVALUATION OF ORGAN DAMAGE IN ACUTE ON CHRONIC LIVER FAILURE (ACLF) PATIENTS

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### Background

Acute on Chronic Liver Failure (ACLF) is an acute deterioration of pre-existing liver disease: an altered response of the organism to hepatic or extrahepatic stress triggers a systemic inflammatory response syndrome (SIRS), then evolving into one or multi-organ failures.

Currently, there is no resolution therapy for liver failure other than transplantation. Liver transplantation is the only treatment option for end-stage liver failure and acute liver failure. Therefore, many liver support extracorporeal therapies (LSET) have been developed offering an opportunity to stabilize liver function while allowing for native liver recovery or as a bridge to transplantation. Among LSET used, hemadsorption is one of the most promising and easy to perform. In the BILIVER study, we want to assess the modulation of bilirubin and other toxic molecules and mediators by hemadsorption and its effects on the severity of organ failure in patients with ACLF.

### Methods

This is a Multicentric Perspective Observational Study.

The population size is 50 patients to be enrolled. For each patient included, the demographic, anamnestic, severity score, clinical parameters and laboratory data will be collected on daily basis, from ICU admission until ICU discharge, according to the routine clinical practice. Blood samples will be collected to assess bilirubin, ammonia, bile acids and cytokine efficacy of removal. The last Follow-up will be at 3 months. In figure 1 is shown the timing of sample measure.

The primary endpoint is the assessment of the removal of major hepatic toxins. the secondary endpoint is the evaluation of effects on clinical outcomes and hepatic recovery.

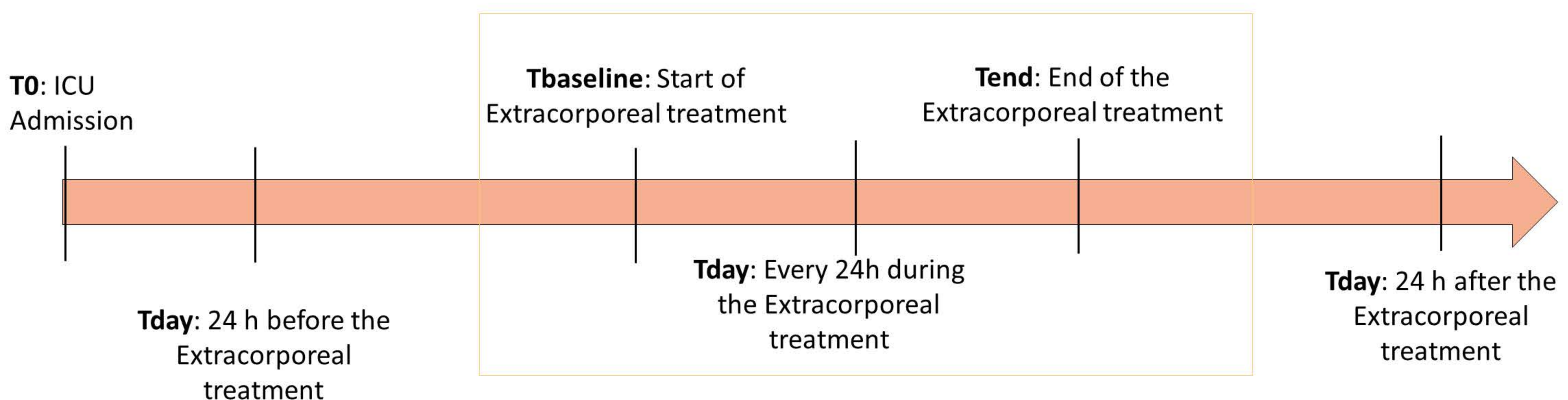


Figure 1: timing of sample measure

### Conclusion

The BILIVER study should help to deepen the knowledge about ACLF and LSET efficacy in a real-life practice, giving the possibility to further improve the management of these complex conditions by the application of hemadsorption support therapy.