

Resource Summary Report

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Mild Hypothermia to prevent Acute kidney injury in Liver Transplantation (MHALT) Trial - Statistical Analysis Plan for the Interim Analysis, v1.0

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Protocol Information

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Summary: Acute kidney injury (AKI), or worsening kidney function, is a common complication after liver transplantation (20-90% in published studies). Patients who experience AKI after liver transplantation have higher mortality, increased graft loss, longer hospital and intensive care unit stays, and more progression to chronic kidney disease compared with those who do not. In this study, half of the participants will have their body temperature cooled to slightly lower than normal (mild hypothermia) for a portion of the liver transplant operation, while the other half will have their body temperature maintained at normal. The study will evaluate if mild hypothermia protects from AKI during liver transplantation. This study is a single-blinded, randomized controlled trial of mild hypothermia during liver transplantation to provide protection from AKI. Participants will be randomized to normothermia (36.5-37.5 °C) versus mild hypothermia (34-35 °C) during a portion of the liver transplant operation. The protocol is based on preliminary data from rodent models showing that hypothermia protects the kidneys from ischemia-reperfusion injury, as well as studies in deceased organ donors showing that cooling improves post-transplant organ function. Temperature will be maintained with standard techniques plus a minimally-invasive esophageal cooling device that is approved by the U.S. Food and Drug Administration. The investigators hypothesize that mild hypothermia will reduce the incidence and severity of AKI after LTx. Standard surrogates (e.g., change in serum creatinine, need for initiation of dialysis) and biomarkers will be used to assess the severity of kidney injury.

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