Neutrophil and Monocyte Deactivation Via the SeLective CytopheretIc Device - A Randomized Clinical Trial in Acute Kidney Injury

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Admitted to an ICU requiring CKRT: 1. Must have AKI stage 2 or greater at the time of CKRT initiation. 2. Must have been on CKRT for at least 12 hours but no greater than 48 hours at the time of enrollment. * At least 18 years of age but not older than 80 at the time of enrollment. * One additional life-threatening organ dysfunction present. * Acceptable vascular access for CKRT to include adequate lumen size and length of catheters. * Initial (non-binding) commitment to maintaining current level of care for at least 96 hours. * C-Reactive Protein \>3.5 mg/dl.

Exclusion Criteria:

* Not expected to survive next 24 hours. * Anticipated transition to comfort measures or hospice in next 4 days. * Terminal condition whereby the patient is not expected to survive 28 days or any condition in which therapy is regarded as futile by the PI. * Advanced malignancy which is actively being treated or may be treated with palliative chemotherapy or radiation. * ICU hospitalization \> 14 days during this hospital admission (to include days spent at ICU of an outside hospital) at the time of screening. * Active COVID-19 infection with a primary admission diagnosis of COVID-19. * Chronic use of ventricular assist devices. * ESRD requiring chronic kidney replacement therapy. * History of CKD (greater than Stage 3). * AKI stage 0 or stage 1 at the time of CKRT initiation. * Non-ATN AKI diagnosis. We intend on relying on local nephrology subspecialty expertise to reasonably exclude non-ATN diagnoses based on clinical suspicions combined with prespecified objective criteria. If there is a reasonable suspicion that the subject has non-ATN AKI based on this, they will be excluded from the trial. * Acute coronary syndromes, acute stroke, or acute major vascular compromise requiring medical or surgical interventions within 48 hours of randomization. * Active hemorrhage requiring blood transfusions at the time of screening. * Acute on Chronic Liver Failure. * Suspicion of hepato-renal syndrome. * Presence of any solid organ transplant at any time prior to admission. * Severe burns with a modified Baux score \> 100 (%TBSA+Age+17 for Inhalation Injury). * Bone marrow transplant within the last year. * Chronic immunosuppression with an average of \>20 mg/day of prednisone or other steroid sparing immunosuppressants for the past 30 days prior to hospital admission. * Individuals who have a history of primary or secondary immune disorders including, but not limited to, HIV or AIDS. * Dry weight of \>150kg. * Platelet count \<15,000/mm3. * Patient is a prisoner or member of a vulnerable population. * Patient is pregnant or breast feeding. * Concurrent enrollment in another interventional clinical trial for an investigational drug or device. * Need for plasmapheresis.

Conditions & Interventions

Interventions:
DEVICE: Selective Cytopheretic Device, OTHER: Standard of Care
Conditions:
Acute Kidney Injury
Keywords:
continuous kidney replacement therapy, continuous renal replacement therapy, acute kidney injury, organ failure, inflammation, dialysis, acute tubular necrosis

More Information

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