Safety Evaluation of Prismocitrate 18 in Patients Receiving CRRT

NCT05399537

Status	RECRUITING
Phase	Phase 3
Sponsor	Vantive Health LLC
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (5)

- Patients must be e18 years of age
- Patients who are candidates for CRRT
- Patients expected to survive for at least 24 hours
- Patients with a contraindication to heparin or an increased risk of hemorrhage
- Patient and/or legally-authorized representative has signed a written informed consent form (ICF) per 21 CFR Part 50.55(e)

Exclusion (7)

- Patients with a known allergy to citrate or who have ever experienced an adverse reaction associated with citrate products, including patients with a prior history of citrate toxicity
- Patients with acute liver failure, defined by the occurrence of encephalopathy and hepatic synthetic dysfunction within 26 weeks of the first symptoms of liver disease and without evidence of chronic liver disease
- Patients with acute-on-chronic liver failure characterized by acute decompensation of cirrhosis and a Child-Pugh Liver Failure Score \>10
- Patients with refractory shock and associated lactic acidosis (lactate \>4 mmol/L)
- Patients with a systemic ionized calcium concentration outside the normal physiologic range (1.0 - 1.3 mmol/L), or outside of the laboratory reference range (Note: It is acceptable to provide calcium supplementation or treatment for hypercalcemia to achieve a normal physiologic range prior to therapy initiation)

... and 2 more (see full listing online)

Locations (14 total)

University of Alabama at Birmingham/UAB, Birmingham, Alabama, United States
University of Southern California (USC) / Keck Hospital, Los Angeles, California, United States
University of California Los Angeles, Los Angeles, California, United States
... and 11 more locations