

Safety and Effectiveness of the Akura Thrombectomy System for Use in the Removal of Emboli From the Pulmonary Arteries in Treating Acute Pulmonary Embolism (PE)

NCT06672510

Status	RECRUITING
Phase	Not Applicable
Sponsor	Akura Medical
Enrollment	118 participants

Key Eligibility Criteria

Inclusion (7)

- The patient is 18 years of age or older and deemed medically eligible for interventional procedure, per institutional guidelines and clinical judgement
- Clinical signs, symptoms and presentation consistent with acute PE
- PE symptom duration \leq 14 days
- CTA evidence of proximal PE (filling defect in at least one main or lobar pulmonary artery)
- CTA evidence of RV/LV ratio of \leq 0.9 (NOTE: Enrollment qualification assessment is based on the Investigator's interpretation of RV/LV ratio at baseline)
- ... and 2 more (see full listing online)

Exclusion (28)

- Prior PE \leq 180 days from index procedure
- Thrombolytic use within 30 days prior to baseline CTA
- Pulmonary hypertension with peak pulmonary arterial pressure (PAP) \geq 70 mmHg by right heart catheterization
- Vasopressor requirement after fluids to keep pressure at \leq 90 mmHg
- FiO₂ requirement \geq 40% or \geq 6 LPM (to keep oxygen saturation \geq 90%)
- ... and 23 more (see full listing online)

Locations (12 total)

Los Robles Regional Medical Center, Thousand Oaks, California, United States
Advanced Heart & Vein (ClinRe-001-001), Thornton, Colorado, United States
Hartford Healthcare, Hartford, Connecticut, United States
... and 9 more locations