

Safety and Effectiveness of the Akura Thrombectomy System in the Treatment of Acute Pulmonary Embolism

NCT06362928

Status	RECRUITING
Phase	Not Applicable
Sponsor	Akura Medical
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (9)

- Patient is ≥ 18 and ≤ 90 years old
- Clinical signs and symptoms consistent with acute PE
- PE symptom duration ≤ 14 days
- CTA evidence of proximal PE (filling defect in at least one main or lobar pulmonary artery as determined by the investigator)
- CTA evidence of RV/LV ratio ≥ 0.9 note: based on Investigator's interpretation of RV/LV ratio at baseline;
- ... and 4 more (see full listing online)

Exclusion (28)

- Prior PE ≤ 180 days from index procedure
- Thrombolytic use ≤ 48 hours prior to baseline CTA
- Pulmonary hypertension with peak pulmonary artery systolic pressure (PASP) ≥ 70 mmHg by right heart catheterization
- Vasopressor requirement after fluids to keep pressure at ≥ 90 mmHg
- FiO₂ requirement $\geq 40\%$ or ≥ 6 LPM to keep oxygen saturation $\geq 90\%$
- ... and 23 more (see full listing online)

Locations (1 total)

Univ.-Klinikum LKH Graz, Graz, Austria