STRIKE-PE: A Prospective, Multicenter Study of the IndigoTM Aspiration System Seeking to Evaluate the Long-Term Safety and Outcomes of Treating Pulmonary Embolism

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- at least 18 years old - diagnosis of acute PE within past 14 days or less

Exclusion Criteria:

- unable to take heparin - Stage III/IV cancer or cancer which requires active chemotherapy - women who are pregnant - other exclusions apply, contact study staff for more information

Conditions & Interventions

Conditions:
Heart & Vascular, Respiratory System
Keywords:
PE, Pulmonary Embolism

More Information

Description: The purpose of this study is to collect information on how patients with PE recover after treatment with the Indigo Aspiration System. The Indigo Aspiration System is a medical device that has been cleared by the U.S. Food and Drug Administration (FDA) for removing blood clots from the blood vessels throughout the body, excluding the head. The device is commercially available globally. Participants will be in this research study for about one year. Participants will be asked to complete a screening and baseline visit, device procedure in-patient visit as part of routine treatment for their PE, one post-procedure visit in the hospital and two follow-up visits. The study team will collect information on tests and procedures done during these visits from their medical records. They will also be asked to complete a quality of life questionnaire.
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