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EKOS™ Endovascular System

HI-PEITHO:
The Higher-Risk Pulmonary Embolism Thrombolysis Study

HI-PEITHO is a multi-center, prospective, randomized, controlled trial in the U.S. and Europe that will compare the outcomes of ultrasound-facilitated, catheter-directed thrombolysis plus anticoagulation vs. anticoagulation alone for the treatment of acute, intermediate-high risk pulmonary embolism (PE).

Principal Investigators: Ken Rosenfield, MD and Stavros Konstantinides, MD, PhD, FESC, FRCP (Glasg)

OBJECTIVE

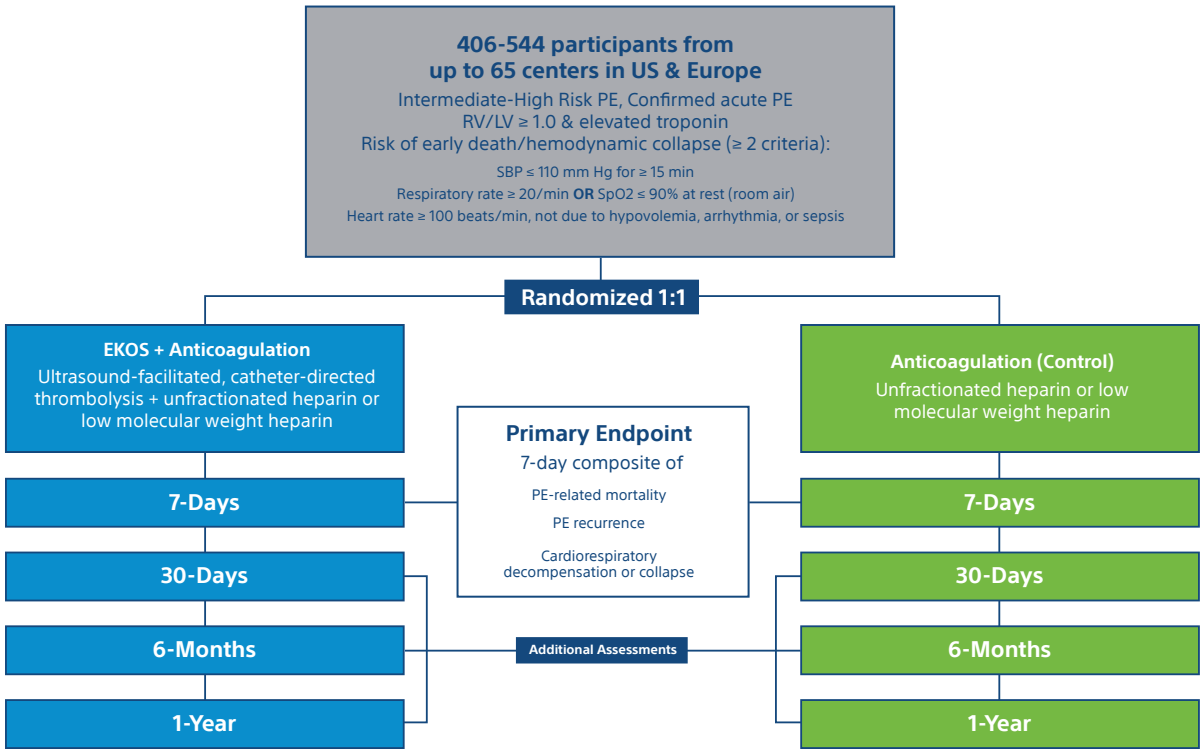
EKOS™ Endovasular System + Anticoagulation vs. Anticoagulation Alone
Evaluate if treatment with EKOS is associated with a significant reduction in the acute composite outcome of the measures below compared to anticoagulation alone –

- PE-related mortality
- PE recurrence (non-fatal symptomatic and objectively confirmed)
- Cardiorespiratory decompensation or collapse

PATIENTS

- Estimated enrollment: 406-544 participants
- Acute intermediate-high risk pulmonary embolism
- RV/LV ≥ 1.0, elevated troponin, & risk of early death/hemodynamic collapse

TRIAL DESIGN



ENDPOINTS

Primary End Points

7-day composite of –

- PE-related mortality
- PE recurrence (non-fatal symptomatic and objectively confirmed)
- Cardiorespiratory decompensation or collapse

Cardiorespiratory decompensation or collapse, defined as at least one of the following:

- Cardiac arrest or need for CPR
- Signs of shock: new onset arterial hypotension with end-organ hypoperfusion
- ECMO placement
- Intubation or noninvasive mechanical ventilation
- National Early Warning Score (NEWS) of 9 or higher

Long Term Follow-Up

Additional follow-ups at 30-days, 6 months, and 1-Year

KEY ADDITIONAL ASSESSMENTS

- Individual primary outcome components
- GUSTO major (moderate and severe) bleeding within 7 days
- International Society on Thrombosis and Haemostasis (ISTH) major bleeding
- Ischemic or hemorrhagic stroke within 7 days and 30 days
- All-cause mortality
- Symptomatic PE recurrence within 30 days and 6 months
- Change from baseline in RV dysfunction on echocardiography at 6 months
- Chronic thromboembolic pulmonary hypertension (CTEPH) diagnosis within 12 months
- Health economic assessments
- Functional status and quality of life measures

IMPORTANCE

The HI-PEITHO study has been designed to address a critical gap in clinical evidence in PE by comparing the clinical benefit of intervention with EKOS vs. the current standard of care – anticoagulation. This trial is the largest and first of its kind in PE. It is designed to generate the most rigorous, highest level of data, contributing to the body of evidence for the treatment and outcomes in acute, intermediate-high risk PE. In addition, HI-PEITHO aims to advance the understanding of intermediate-high risk PE and risk stratification, to better identify patients who may clinically benefit from intervention, expanding access to care for these patients.

For more information visit clinicaltrials.gov

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