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EKOS™ Endovascular System

HI-PEITHO

Multinational, multicenter randomized controlled trial comparing EKOS™ Ultrasound-assisted catheter-directed thrombolysis (USCDT) plus anticoagulation (AC) to AC alone for the treatment of intermediate-risk acute pulmonary embolism

9 Countries

59 Enrollment Sites

544 Patients

Primary Endpoint
Composite measure of PE-related mortality, cardiorespiratory decompensation or collapse, and non-fatal symptomatic PE recurrence at 7 days

HI-PEITHO Patient Profile

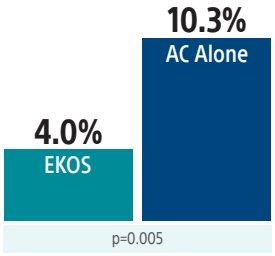
	Patients	Age	% Female	RV/LV	Baseline NEWS
EKOS	273	58.2 ± 13.6	42%	1.6 ± 0.5	6 ± 1.9
AC Alone	271	58.2 ± 13.4	44%	1.5 ± 0.4	6 ± 1.9

HI-PEITHO EKOS Protocol

- Infusion Time: 7 hours
- Unilateral: 9mg r-tPA total | 2mg bolus + 1mg/hr.
- Bilateral: 18mg r-tPA total | 2mg bolus + 1mg/hr.

Patients Treated with EKOS Had Superior Clinical Outcomes With No Increase in Major Bleeding and Zero ICH Events

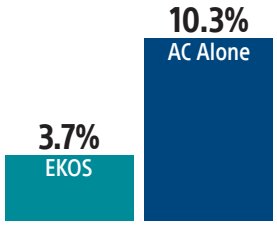
Primary Endpoint



EKOS significantly reduced the incidence of the primary composite endpoint

Two-sided P-value using Fisher's exact test; P-value <0.02938 indicates significance

Cardiorespiratory Decompensation or Collapse



Treatment with **EKOS reduced cardiorespiratory decompensation** or collapse by 64%

Major Bleeding at 30 Days

ISTH[1]

4.1% EKOS n=271 | **3.0%** AC Alone n=271 | **0** ICH Events in Either Study Arm

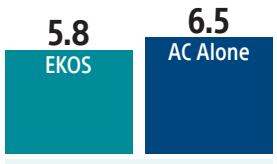
p=0.64

There was **no significant difference in major bleeding** between treatment arms

[1]ISTH: International Society on Thrombosis and Haemostasis

Hospital Total Length of Stay

Days



Total LOS **was significantly shorter** for patients treated with EKOS

LEVEL-1 EVIDENCE

HI-PEITHO is the first major randomized controlled trial with clinically meaningful endpoints comparing catheter intervention to standard of care in PE, **demonstrating clinical benefit without additional risk.**

What is the NEWS?

The National Early Warning Score (NEWS) is a standardized and easy-to-use tool that determines the degree of illness and mortality risk of a patient and can be used to prompt critical care intervention.

NEWS is an increasingly popular tool that has been recommended by the National Health System of the United Kingdom for initial assessment, serial monitoring, and patient triage. **NEWS has also been validated and adopted by hospitals in other countries including the United States.**

NEWS provides a scoring system for physiological measurements that are routinely recorded at a patient's bedside. A score ranging from 0-3 is allocated to each parameter, with higher scores indicating the parameter is further from the normal range. The scores for each parameter are then added together to determine the NEWS Score.

HI-PEITHO is the first randomized controlled trial within the PE space to include NEWS as part of the trial protocol.

NEWS in HI-PEITHO

- **NEWS ≥ 9 = cardiorespiratory decompensation or collapse**
  - Between 24 hours and 7 days after randomization
  - Confirmed on 2 consecutive measures 15 minutes apart
- **NEWS ≥ 9 was prespecified as an ethical endpoint to allow rescue therapy while preventing bias from premature crossover**
  - This protocol maximized patient safety while ensuring integrity of the trial's results

Physiological Parameters	Score						
	3	2	1	0	1	2	3
Respiration Rate	≤8		9 – 11	12 – 20		21 – 24	≥25.0
Oxygen Saturations	≤91	92 – 93	94 – 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35		35.1 – 36.0	36.1 – 38.0	38.1 – 39.0	≥ 39.1	
Systolic Blood Pressure	≤90	91 – 100	101 – 110	111 – 219			≥220
Heart Rate	≤40		41 – 50	51 – 90	91 – 110	111 – 130	≥131
Level of Consciousness				A			V, P, or U

NEWS	Clinical Risk	Response
Aggregate score 0–4	Low	Ward-based response
Red score: Score of 3 in any individual parameter	Low-medium	Urgent ward-based response
Aggregate score 5–6	Medium	Key threshold for urgent response
Aggregate score 7 or more	High	Urgent or emergency response

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Interventional Cardiology & Vascular Therapies

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