

## HOME-PE - Hospitalization or Outpatient Management of PE Patients - HESTIA vs. Simplified PESI

**Purpose:** The main objective is to demonstrate, in normotensive pulmonary embolism (PE) patients, that a strategy based on the HESTIA rule compared to a strategy based on the simplified PESI score is at least as safe as regards the 30-day-rate of adverse events (recurrent VTE, major bleeding or death).

**Trial Design:** N = 1975, open-label, controlled randomized international trial with blinded adjudication of endpoints

**Primary Endpoint:** The rate of the composite of recurrent VTE, major bleeding and all cause death at 30 days

- Recurrent VTE: objectively confirmed pulmonary embolism or deep venous thrombosis objectively confirmed.
- Major bleeding: according to the International Society on Thrombosis and Haemostasis' criteria.
- Death: all-cause mortality.

**Secondary Endpoints Included:** The rate patients managed as outpatients, the rate of low-risk patients in theory eligible for outpatient care, rate of cumulative events, recurrent VTE, suspected recurrent VTE, major bleeding, non major bleeding, death, serious adverse events.

	HESTIA strategy N=378	sPESI strategy N=361	
	Intention to treat patients		
Clinical events at day 30	N* of patients with event/total n* of patients (%)		
Composite of recurrent VTE, major bleeding, and all-cause death	5/375 (1.33)	4/359 (1.11)	0.19% (-1.15 to 1.52)
Recurrent VTE	0/374 (-)	2/358 (0.56)	-0.26% (-0.63 to 0.10)
Major bleeding	5/375 (1.33)	1/358 (0.28)	1.07% (-0.38 to 2.53)
All-cause death	1/375 (0.27)	1/359 (0.28)	-0.01% (-0.36 to 0.35)

Conclusion: For outpatient care of normotensive PE patients, the triaging strategy based on the pragmatic rule, HESTIA, was non inferior to the strategy based on the severity risk assessment score, sPESI, with respect to the composite end point of recurrent venous thromboembolism, major bleeding and death. The two strategies do not significantly differ with respect to the proportion of patients managed at home or early discharged.

