Hospitalization or Outpatient ManagEment of patients with Pulmonary Embolism: a randomized controlled trial - HOME-PE

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Main safety objective: To demonstrate, in normotensive 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,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON45665

Source
ToetsingOnline

Brief title
HOME-PE

Condition

- Embolism and thrombosis

Synonym
pulmonary embolism blood clots in the lung

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,aangevraagd

Intervention

Keyword: pulmonary embolism - triage - home treatment

Outcome measures

Primary outcome

Primary safety endpoint:

The composite rate of recurrent VTE, major bleeding and death at 30 days

following the inclusion:

- 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.

Primary efficacy endpoints:

1) The rate of *low-risk* patients eligible for outpatient care:

- HESTIA group: patients meeting none of the exclusion criteria of the rule

(HESTIA rule negative);

- sPESI group: patients with a simplified PESI score =0.

2) The rate of patients managed as outpatients defined by patients discharged

home within 24 hours after the inclusion in the study.

Secondary outcome

• Safety endpoints:

- The rate of recurrent VTE,

- The rate of major bleeding,

- All-cause mortality.

• Applicability endpoint:

- The rate of patients eventually managed as outpatients among patients

eligible for outpatient care (i.e. patients meeting all the criteria of the

rule in the HESTIA group and patients with a simplified PESI score =0 in the

sPESI group).

• Resource utilization endpoint:

- Mean cumulative hospital length of stay for initial hospitalization and

unscheduled hospitalizations in the 30 days following admission.

• Patients satisfaction and quality of life:

- Patient-reported Pulmonary Embolism Quality of Life Questionnaire and

Anti-Clot Treatment Questionnaire at 30 days following inclusion.

Study description

Background summary

Several studies have demonstrated the possibility of outpatient management or early discharge for certain patients presenting acute pulmonary embolism (PE), providing a suitable structure is in place.1 2 However, controversy persists about the optimal referral strategies and eligibility criteria for outpatient care.
The approach featured in the most recent guidelines on acute PE of the European Society of Cardiology,3 refers to an all-cause mortality risk assessment using the Pulmonary Embolism Severity Index (PESI) score or the simplified PESI score (sPESI).4 The sPESI takes into account demographics (age), patient history (cancer, cardiac or respiratory disease), and clinical data (systolic blood pressure, heart rate, oxygen saturation).5 Outpatient care is offered to low-risk patients, providing that all the conditions pertaining to start anticoagulant treatment and follow-up at home are met.3
Recently, an alternative approach based on a list of simple criteria has been

developed as the one used in HESTIA study.6 The main criteria included in the HESTIA rule consist of absence of the following: hemodynamic instability, need for oxygen therapy, high-risk of haemorrhage, renal failure, liver failure, or other medical or social conditions requiring hospitalization.6
Even though the proportion of *low-risk* PE patients eligible for outpatient care and the proportion of patients treated at home seem higher, the rate of complications does not seem to be increased when applying a strategy based on HESTIA rule, as compared to the PESI or simplified PESI score.4 6 These comparisons are however indirect and the two rules have never been compared face to face.
We hereby propose comparing these two approaches in an open-label, controlled randomized international trial with blinded adjudication of endpoints.

Study objective

Main safety objective: To demonstrate, in normotensive 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).

Main efficacy objective: To demonstrate, in normotensive PE patients, that a strategy based on the HESTIA rule compared to a strategy based on the simplified PESI score is more effective:
As regards the rate of patients eligible for outpatient care,
As regards the rate of patients eventually managed as outpatients.

Study design

HOME-PE is a randomized controlled randomized multicentre international trial with non-inferiority analysis for the main safety judgment criterion (rate of adverse events) and superiority analysis for the two efficacy judgment criteria (rate of patients eligible for outpatient care and percentage of patients eventually treated as outpatients).
In the participating centres, specific structures based on a *thrombosis team* for outpatient care of PE patients will be set up prior to study initiation.

All patients admitted in the Emergency Department of the participating centres and diagnosed with PE will be eligible and assessed for potential inclusion.

Included patients will be randomized into two groups (1:1) and stratified by centre. Data will be recorded in a computerized case report form (e-CRF) enabling the randomization.

The HESTIA group will receive outpatient care proposal based on HESTIA criteria. The sPESI group will receive outpatient care proposal based on the simplified PESI score. Any reason for management (hospitalization or outpatient

treatment) not based on the recommendation must be explained and documented in the e-CRF.

Follow-up will occur within 72 hours after inclusion, at 14 days, 1 month, and 3 months in both groups to gather clinical event data (recurrent VTE, major bleeding, death), treatment data, unscheduled hospitalizations and patient satisfaction assessment results.

An independent adjudication committee will evaluate all possible endpoints blinded to the group allocation.
An independent data and safety monitoring board will periodically review the study outcomes and advise the investigators.

Intervention

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Study burden and risks

not applicable

Contacts

Public
Leids Universitair Medisch Centrum

albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Admission to Emergency Department in one of the participating centres;
Established pulmonary embolism diagnosis according to the European Society of Cardiology criteria;
Insurance cover according to local legislation;
Age >=18 years;
Orally given or signed informed consent (according to local legislation)

Exclusion criteria

Shock or hypotension defined as systolic blood pressure <90 mmHg or a systolic pressure drop by >=40 mmHg, for >15 minutes, if not caused by new-onset arrhythmia, hypovolaemia, or sepsis.
Diagnosis of pulmonary embolism established over 24H before inclusion;
More than 48h between first presentation to the Emergency unit and inclusion;
Impossibility for 30-day follow-up

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2017
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	20-06-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved

Date:	12-01-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-10-2018

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02811237
CCMO	NL59541.058.17

Study results

Date completed:	07-07-2019
Actual enrolment:	194

Summary results
Trial is onging in other countries