SSPE * The Management of Subsegmental Pulmonary Embolism: A Prospective Cohort Study

Published: 05-10-2016
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See chapter 'objectives' of study protocol (page 12)

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

Summary

ID

NL-OMON43375

Source
ToetsingOnline

Brief title
SSPE-study

Condition

- Embolism and thrombosis

Synonym
Pulmonary embolism, venous thromboembolism

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: standaard zorg

Intervention

Keyword: Pulmonary embolism, Subsegmental, Treatment

Outcome measures

Primary outcome

See chapter 'endpoints' of study protocol (page 14-16)

Secondary outcome

See chapter 'endpoints' of study protocol (page 14-16)

Study description

Background summary

See chapter 'introduction' of study protocol (page 8-12)

Study objective

See chapter 'objectives' of study protocol (page 12)

Study design

See chapter 'design' of study protocol (page 12)

Intervention

See chapter 'intervention' of study protocol (page 14)

Study burden and risks

See chapter ' Benefits and risk assessment, group relatedness' of study protocol (page 24)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Patients with newly diagnosed isolated SSPE (any number). Isolated SSPE is defined as CTPA demonstrating an intraluminal filling defect in a subsegmental artery with no filling defects visualized at more proximal pulmonary artery levels.
2) Signed and dated informed consent of the subject available before the start of any specific study procedures;
3) Age *18 years.

Exclusion criteria

1) Concomitant Proximal lower extremity (popliteal vein or above) or upper extremity (subclavian vein or above) DVT.
2) Need for long term oral anticoagulant therapy for reasons other than VTE.
3) SSPE diagnosed in a hospitalized patient (> 48 hours after hospital admission).
4) Requiring oxygen therapy to maintain an O2 saturation over 92%
5) Previous history of DVT (proximal or distal) of upper or lower extremities, PE, or unusual site thrombosis (e.g. splanchnic or cerebral vein thrombosis).
6) Active Malignancy (defined as other than basal-cell or squamous cell carcinoma of the

skin; cancer within the past 6 months; any treatment for cancer in the past 6 months; or recurrent or metastatic cancer)
7) Pregnancy
8) Have received more than 48 hours of therapeutic anticoagulation. Prophylactic dose allowed if required for separate indication AND acceptable by the investigator.
9) Unable/refuse to sign informed consent or Geographically inaccessible for follow-up

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2016
Application type:	First submission
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	NCT01455818
CCMO	NL56148.058.16

Study results

Date completed: 08-02-2021

Actual enrolment: 10

Summary results
Trial is onging in other countries