Vesta Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24317

Source
NTR

Brief title
Vesta Study

Health condition

Pulmonary embolism
Outpatient treatment

In dutch:
longembolie
thuisbehandeling

Sponsors and support

Primary sponsor: Leiden University Medical Centre,
Leiden, The Netherlands
Source(s) of monetary or material Support: Leiden University Medical Centre,
Leiden, The Netherlands

Intervention

Outcome measures

Primary outcome

30 day adverse outcome defined as occurrence of any of the following:

1. PE or major bleeding related mortality;

2. Cardiopulmonary resuscitation;

3. Mechanical ventilation;

4. Use of vasopressors;

5. Thrombolytic therapy given;

6. Thrombosuction;

7. Open surgical embolectomy;

8. PE or major bleeding related admission to IC unit.

Secondary outcome

1. Recurrent venous thromboembolism;

2. Major bleeding and all-cause mortality during three months;

3. Also ten day mortality due to PE or its treatment and ten day adverse outcome defined as occurrence of any of the following: PE or major bleeding related mortality, cardiopulmonary resuscitation, mechanical ventilation, use of vasopressors, thrombolytic therapy given, thrombosuction, open surgical embolectomy or PE or major bleeding related admission to IC unit are considered as secondary endpoints.

Study description

Background summary

Several cohort studies have suggested that home treatment in pulmonary embolism is feasible and safe in patients at low risk for adverse outcome. However it is debated which strategy of risk stratification is optimal for selecting these low-risk patients. Prospective studies in which different strategies on risk stratification are compared are lacking. Therefore the purpose of our study is to compare two strategies for risk stratification of patients with PE to determine if the strategy based on signs and symptoms alone (Hestia strategy) is as safe as the strategy based on signs, symptoms and a biomarker NT-proBNP for selection of patients for outpatient treatment.

In this study consecutive patients with proven acute PE are triaged for possibility of

treatment out of the hospital. Patients are selected for outpatient treatment according to the previously studied Hestia rule. Patients eligible for outpatient treatment are randomized for one of two risk stratification schemes: (A) with or (B) without NT-proBNP. Patients in group A are sent home only if the value of proBNP is low. Patients with a high NT-proBNP value are admitted to the hospital. Patients in group B are sent home without additional laboratory testing. Venous blood will be stored for proBNP testing after completion of the study. Primary endpoint is 30 day adverse outcome, including hemodynamic instability, IC admission and PE or major bleeding related death. Secondary outcome is recurrent venous thromboembolism (VTE), major bleeding and all-cause mortality during three months.

Study objective

To investigate whether outpatient treatment based on the Hestia rule is as safe as a strategy based on the Hestia rule and the NT-proBNP biomarker in patients with PE.

Study design

Patients are seen at the outpatient clinic at 1 week after the index PE and 4-6 weeks after the index event. Three months after the index PE they are contacted by telephone.

Intervention

Patients with acute PE not applying to one of the criteria of the Hestia rule are randomized in two treatment strategy groups:

1. Outpatient treatment;

2. Outpatient treatment depending on NT-proBNP levels.

Contacts

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Eligibility criteria

Inclusion criteria

Consecutive patients with proven acute, hemodynamically stable PE, i.e. PE that does not warrant thrombolytic therapy, presenting to the emergency department or to the outpatient clinic. Patients with provoked and unprovoked PE are eligible.

Exclusion criteria

1. Age less than 18 years;

2. Acute onset or acute worsening of symptoms indicative of PE lasting for more than 14 days;

3. Active bleeding, or a very high risk for major bleeding, i.e. gastro-intestinal bleeding in the preceding 14 days, recent stroke (less than 4 weeks ago), recent operation (less than 2 weeks ago, when in doubt bleeding risk can be assessed in consultation with the surgeon), bleeding disorder, thrombocytopenia (platelet count < 75 x 109/L) or uncontrolled hypertension (systolic blood pressure > 180 mm Hg or diastolic blood pressure > 110 mm Hg);

4. PE accompanied by hemodynamic instability. The criteria for instability include the following: systolic blood pressure < 100 mmHg with heart rate > 100 beats per minute; possibly in combination with one or more of the following symptoms of organ perfusion defects: oliguria, pale skin or elevated lactate levels in arterial blood gas analysis, altered mental state, or any other PE related condition requiring admission to an intensive care unit;

5. Acute PE requiring thrombolytic treatment or pulmonary embolectomy;

6. Requirement for oxygen therapy to maintain oxygen saturation greater than 90%;

7. Severe pain requiring intravenous narcotic analgesia;

8. Medical or social condition which necessitates admission to the hospital for another reason (for example infection, cancer or stroke) without discharge in the next 24hours;

9. Diagnosis of PE during anticoagulant treatment (prophylactic doses of LMWH are allowed);

10. Severe renal failure e.g. calculated creatinine clearance < 30 ml/min. Cockcroft-Gault formula or MDRD is acceptable;

11. Pregnancy;

12. Previously documented heparin induced thrombocytopenia;

13. Severe liver failure (according judgement of physician);

14. Likelihood of non-compliance (e.g. no fixed address);

15. Life expectancy less than three months;

16. Participation in this study during a previous episode of acute PE;

17. Participation in another therapeutic trial (diagnostic studies are allowed);

18. Failure to sign informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010

Enrollment:	530
Type:	Actual

Ethics review

Positive opinion

Date:	12-11-2010
Application type:	First submission

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
NTR-new	NL2486
NTR-old	NTR2603
Other	METC LUMC : P10-096
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A