Efficacy and safety of home treatment versus in hospital treatment with LMWH in patients with non-massive pulmonary embolism

No registrations found.

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

Summary

ID

NL-OMON22733

Source
Nationaal Trial Register

Brief title
Hestia study

Health condition

Pulmonary embolism
Home treatment
Low-molecular-weight-heparin

And in Dutch:
Longembolie
Thuisbehandeling
Laag-moleculair-gewicht-heparine

Sponsors and support

Primary sponsor: Leiden University Medical Center,
Department of General Internal Medicine-Endocrinology
Source(s) of monetary or material Support: All participating hospitals give financial support.

Unrestricted research grant: GlaxoSmithKline

Intervention

Outcome measures

Primary outcome

Efficacy and safety of home treatment

1. Recurrent thromboembolic events are defined as recurrent pulmonary embolism if demonstrated by new defects on helical CT scan, perfusion-ventilation lung scan or pulmonary angiography or PE at autopsy or a clinical report indicating PE as the (likely) cause of death; or deep vein thrombosis demonstrated by compression ultrasonography or contrast venography.

2. Bleeding is defined as major if it is clinically overt e.g. a clinically apparent bleeding or sign and symptoms suggestive of bleeding confirmed with imaging studies (ultrasound, computer tomography (CT)) combined with at least one of the following situations:

a) Critical site involvement e.g. intracranial, retroperitoneal, intraocular, intraspinal, pericardial or non-traumatic intra-articular.

b) Bleeding associated with a decrease in hemoglobin level of 1.3 mmol/L (2.0 gr/dl) or more.

c) Bleeding leading to transfusion of > 2 units of whole blood or packed red cells.

d) Fatal bleeding.

3. The cause of death in patients who die within the study period is assessed by autopsy or a clinical report indicating the – likely - cause of death.

Secondary outcome

A health economics evaluation in all patients

Study description

Background summary

While evidence is accumulating that initial home treatment of patients with acute PE may be feasible and safe, no study has conclusively demonstrated effective and safe out of hospital treatment in patients with acute PE. Given this limited evidence, clinicians remain reluctant

to routinely treat patients with non-massive pulmonary embolism at home with LMWH and as a result, nearly all patients presenting with acute PE still receive initial treatment at the hospital.

The purpose of the current study is to evaluate the efficacy and safety of out of hospital LMWH treatment in consecutive patients with acute non-massive PE. In addition, a health economics evaluation will be performed.

Study objective

Outpatient LMHW treatment in patients with objectively proven non-massive pulmonary embolism is efficacious and safe.

Study design

One week, six weeks and three months after diagnosis.

Intervention

Patients with objectively proven PE will be triaged for possibility of treatment with LMWH out of the hospital.

Initial anticoagulant treatment with LMWH can be started on the basis of the clinical symptoms of the patient and consists of subcutaneous injections once daily for a minimum of five days. All patients who can be treated at home are sent home either immediately or within 24 hours after PE is objectively diagnosed.

Contacts

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Eligibility criteria

Inclusion criteria

1. Consecutive patients with proven acute non-massive, stable Pulmonary Embolism (PE), i.e. PE that does not warrant thrombolytic therapy, presenting to the emergency ward or to the outpatient clinic.

2. Patients with provoked and non-provoked (‘idiopathic’) pulmonary embolism and patient with a first as well as those with a recurrent episode of pulmonary embolism are considered eligible for the study.

Exclusion criteria

1. Patients who have had symptoms of PE for longer than 7 days duration

2. 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), bleeding disorder, or thrombocytopenia (platelet count < 75 x 109/L)

3. PE accompanied by hemodynamic instability. The criteria for instability are left to the discretion of the investigator.

4. Massive PE requiring thrombolytic treatment or pulmonary embolectomy

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

6. Severe pain requiring intravenous narcotic analgesia

7. 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

8. Severe renal failure e.g. calculated creatinine clearance < 30 ml/min.

9. Severe liver failure
10. Diagnosis of PE during anticoagulant treatment

11. Previously documented heparin induced thrombocytopenia

12. Pregnancy

13. Age less than 18 years

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

15. Life expectancy less than three months

16. Failure to sign informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2008
Enrollment:	260
Type:	Actual

Ethics review

Positive opinion

Date:	22-05-2008
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	NL1273
NTR-old	NTR1319
Other	METC LUMC : P07-244
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A