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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22733

Bron
Nationaal Trial Register

Verkorte titel
Hestia study

Aandoening

Pulmonary embolism
Home treatment
Low-molecular-weight-heparin

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center,
Department of General Internal Medicine-Endocrinology

Overige ondersteuning: All participating hospitals give financial support.

Unrestricted research grant: GlaxoSmithKline

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

One week, six weeks and three months after diagnosis.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-05-2008
Aantal proefpersonen:	260
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-05-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1273
NTR-old	NTR1319
Ander register	METC LUMC : P07-244
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A