Prometheus-Study: Diagnostics.

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1. To assess four different clinical decision rules (Wells rule, revised Geneva decision rule, simplified Wells rule and simplified revised Geneva decision rule) in the exclusion of pulmonary embolism; 2. To evaluate the safety of withholding...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26276

Bron
Nationaal Trial Register

Aandoening

Pulmonary embolism
diagnosis
clinical decision rule

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: geen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(Recurrent) pulmonary embolism or deep vein thrombosis.

Toelichting onderzoek

Achtergrond van het onderzoek

The object of this study is to evaluate four clinical decision rules in the exclusion of pulmonary embolism (Wells rule, revised Geneva score, simplified Wells rule and simplified revised Geneva score). They will be evaluated for safety and clinical utility, both alone and in combination with a D-dimer test. Also, the clinical decision rule according to Wells is evaluated in patients with a suspected recurrent pulmonary embolism: whether it is safe to withhold anticoagulant treatment in patients in whom suspected recurrent pulmonary embolism is excluded based on an unlikely Wells score combined with a normal D-dimer test.

Doel van het onderzoek

1. To assess four different clinical decision rules (Wells rule, revised Geneva decision rule, simplified Wells rule and simplified revised Geneva decision rule) in the exclusion of pulmonary embolism;

2. To evaluate the safety of withholding anticoagulant treatment in patients in whom recurrent PE is excluded on the basis of a pre-specified algorithm (using the Wells rule).

Onderzoeksopzet

Moment of diagnostic workup for PE and 3 month follow up (one telephone call).

Onderzoeksproduct en/of interventie

In case of a first PE, a CT scan is performed in the following combination of tests:

1. Decision rules disagree with each other (one (or more) indicating ‘unlikely’ probability, other(s) indicating a ‘likely’ probability);

2. All four decision rules indicate a ‘likely' probability for PE;

3. All four decision rules indicate an ‘unlikely’ probability for PE but D-dimer is abnormal.

In case of a recurrent pulmonary embolism, the Wells rule will prefer, a CT is performed in case of (figure 1b):

1. A high probability of the Wells score;

2. A combination of a low probability of the Wells score and an abnormal D-dimer.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Out- or inpatients with a first episode of clinically suspected pulmonary embolism;

2. Suspected recurrent pulmonary embolism for study question B.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years;

2. Life expectancy < 3 months;

3. Treatment with full-dose therapeutic low molecular weight heparin or unfractionated heparin that was initiated 24 hours or more prior to eligibility assessment;

4. Treatment with vitamin K antagonists (coumarin derivates);

5. Contraindication to helical CT:

A. Allergy to intravenous iodinated contrast;

B. Renal insufficiency (creatinine clearance < 30 ml/min);

C. Pregnancy;

D. Impossibility to return for follow-up.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2008
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-01-2010
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	NL2068
NTR-old	NTR2185
Ander register	METC LUMC Leiden : P07.266
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A