Simple and safe exclusion of pulmonary embolism using quantitative D-dimer and Wells simplified decision rule.

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Excluding PE by a CDR indicating PE unlikely, assessed by the Wells simplified decision rule, combined with a normal D-dimer is safe and efficient.

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

Samenvatting

ID

NL-OMON25993

Bron
NTR

Verkorte titel
N/A

Aandoening

Clinically suspected pulmonary embolism.

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: unrestricted grants from the participating hospitals

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patients, in whom pulmonary embolism was excluded, were followed up for 3 months to

document the occurrence of venous thromboembolic events or death.

Toelichting onderzoek

Achtergrond van het onderzoek

In conclusion, this large study has prospectively demonstrated the safety of excluding pulmonary embolism by the use of a dichotomous clinical decision rule and D-dimer test in patients with suspected pulmonary embolism. We have established that by implying such a non-invasive strategy anticoagulant therapy can safely be withheld with great efficiency involving more than 50 % of patients, thus obviating the need for more invasive and costly tests, including CT scan and perfusion lung scan. The standard approach in the diagnostic management of PE should now be to start with a clinical decision rule and a quantitative D-dimer test and rely on the outcome of these two tests. If the clinical decision rule indicates PE to be likely present or if the D-dimer test is abnormal, further imaging tests are warranted.

Doel van het onderzoek

Excluding PE by a CDR indicating PE unlikely, assessed by the Wells simplified decision rule, combined with a normal D-dimer is safe and efficient.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Upon clinical suspicion, Wells clinical decision rule was performed first and if patients had a score of 4.0 points, a D-dimer test followed. Patients with a normal D-dimer concentration had no further tests, pulmonary embolism was considered excluded and patients did not receive anticoagulant treatment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Outpatients with clinically suspected PE.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Anticoagulant therapy for more than 24 hours;

2. aged under 18 years;

3. pregnancy;

4. allergy to contrast media;

5. expected survival less than 3 months;

6. venous thromboembolism in the previous 6 months;

7. refusal or inability to consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2002
Aantal proefpersonen:	879
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2006
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	NL747
NTR-old	NTR757
Ander register	: N/A
ISRCTN	ISRCTN10533382

Resultaten

Samenvatting resultaten
Thromb Haemost. 2007 Jan;97(1):146-50.