

Prometheus-Study: Diagnostics.

No registrations found.

| | |
|------------------------------|----------------------------|
| Ethical review | Positive opinion |
| Status | Recruiting |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON26276

Source

NTR

Health condition

Pulmonary embolism
diagnosis
clinical decision rule

Sponsors and support

Primary sponsor: LUMC

Source(s) of monetary or material Support: geen

Intervention

Outcome measures

Primary outcome

(Recurrent) pulmonary embolism or deep vein thrombosis.

Secondary outcome

Performance of four clinical decision rules.

Study description

Background summary

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.

Study objective

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).

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Out- or inpatients with a first episode of clinically suspected pulmonary embolism;
2. Suspected recurrent pulmonary embolism for study question B.

Exclusion criteria

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 derivatives);
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.

Study design

Design

| | |
|---------------------|----------------------------|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-07-2008 |
| Enrollment: | 800 |
| Type: | Anticipated |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 27-01-2010 |
| 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 | NL2068 |
| NTR-old | NTR2185 |
| Other | METC LUMC Leiden : P07.266 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

Study results

Summary results

N/A