Evaluatie van biomarkers bij VTE onderzoek; de EVA studie

No registrations found.

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

Summary

ID

NL-OMON29132

Source
Nationaal Trial Register

Brief title
EVA

Health condition

Deep Venous Thrombosis, Pulmonary Embolism, D-dimer, Point-of-Care biomarker, primary care

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Nano-ditech corporation USA
Roche Diagnostics The Netherlands
De Friesland Insurance Company

Intervention

Outcome measures

Primary outcome

proximal DVT of the leg or Pulmonary Embolism

Secondary outcome

additional diagnostic information of (cardiac) biomarkers

Study description

Background summary

Venous thrombo-embolism (VTE), i.e. deep vein thrombosis (DVT) or pulmonary embolism (PE), poses a major diagnostic challenge for the general practitioner (GP) because signs and symptoms can be non-specific and even often quite minimal. The diagnostic work-up starts with scoring a clinical decision rule (CDR). If the CDR yields a low score (low VTE probability) a negative D-dimer test result can safely rule-out VTE without referral for imaging. However, the usability of this diagnostic approach is hampered in two clinical situations. First, D-dimer levels increase with increasing age (more false positives) and recently an age adjusted cut-off level for D-dimer test results was proposed to increase the diagnostic yield of D-dimer (i.e. better rule-out VTE) in elderly patients. Second, the most important differential diagnosis of VTE is an infectious disease (community-acquired pneumonia in the case of a primary suspicion of PE, or erysipelas in the case of a primary suspicion of DVT). In these cases, due to inflammation, D-dimer levels are also increased, in the absence of VTE, again decreasing the diagnostic yield of D-dimer.

The primary objective of this study is to perform a clinical and analytical validation of novel point-of-care (POC) D-dimer assays, in particular regarding their ability to rule-out VTE using an age-adjusted D-dimer cut-of. Secondary objectives are evaluating the added diagnostic information as obtained from inflammatory biomarkers (C-reactive protein and procalcitonin). Finally, we want to evaluate a novel biomarker for coagulation that has recently been developed (e.g. thrombin-anti-thrombin complex; TAT). We hypothesize that TAT-levels more accurately predict actual coagulation, and thus likely suffer less from false positive findings due to ageing or concurrent infectious diseases. For this purpose additional blood will be sampled and stored centrally in the “biobank” of the UMC Utrecht, allowing for future analyses for emerging novel biomarkers.

Study design

3 months

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

suspected DVT or PE with a low score on the Clinical Decision Rule

Exclusion criteria

age below 18, a high score on the CDR, ongoing anticoagulation, unable or unwilling to provide informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	750
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46107
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5974

Register	ID
NTR-old	NTR6348
CCMO	NL56475.041.16
OMON	NL-OMON46107

Study results