Evaluatie van biomarkers bij VTE onderzoek; de EVA studie

Gepubliceerd: 20-11-2016 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON29132

Bron
Nationaal Trial Register

Verkorte titel
EVA

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Nano-ditech corporation USA
Roche Diagnostics The Netherlands
De Friesland Insurance Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

proximal DVT of the leg or Pulmonary Embolism

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

3 months

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Julius Centrum voor Gezondheidswetenschappen en Eerstelijns Geneeskunde,Stratenum 6.131

R. Oudega
Universiteitsweg 100

Utrecht 3584 CG
The Netherlands
06-53152059

Wetenschappelijk

Julius Centrum voor Gezondheidswetenschappen en Eerstelijns Geneeskunde,Stratenum 6.131

R. Oudega
Universiteitsweg 100

Utrecht 3584 CG
The Netherlands
06-53152059

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	750
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46107
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5974

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

Resultaten