'Evaluatie van biomarkers in VTE studie met capillair bloed monster; de EVA-II studie'

Gepubliceerd: 28-12-2020 Laatst bijgewerkt: 15-05-2024

N/A

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

Samenvatting

ID

NL-OMON26166

Bron
NTR

Verkorte titel
EVA-II

Aandoening

Venous thrombosis, pullmonary embolism

Ondersteuning

Primaire sponsor: Jeroen Bosch Hospital
Overige ondersteuning: Aksa Medical, The Netherlands; The Netherlands; Mediphos, The Netherlands,

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is an analytic validation of D-dimer tests with capillary

whole blood of six different, recently introduced POC laboratory devices compared with a central routine lab D-dimer assay.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Venous thrombo-embolism (VTE) can be ruled-out in Primary Care in patients with a low score on a clinical decision rule (CDR) and a negative D-dimer test result without the need for referral for imaging. Very recently, new Point-of-Care laboratory devices have been introduced enabling low-volume capillary blood sampling, suitable for rapid exclusion of VTE in primary care.
Objectives: Primary objective of this study is to perform an analytical validation of five novel point-of-care (POC) D-dimer assays compared with a routine lab D-dimer assay. Secondary objectives are a clinical validation according to VTE diagnosis, since a Gold Standard of D-dimer is lacking and testing the additional value of other biomarkers.

Study design and study population: Prospective cohort study in patients suspected of having VTE who are referred to a hospital- or primary care laboratory for a lab D-dimer testing. After written Informed Consent, an additional blood sample will be extracted from the venipuncture that will be used for routine D-dimer testing in order to prepare plasma for a central D-dimer measurement at the Jeroen Bosch Hospital at ‘s-Hertogenbosch. In addition, a POC D-dimer test will be done using a capillary blood sample drawn from a finger prick.
Three months after the blood draw, the GP will be enquired for the diagnosis of the coded patient. The experimental intervention under study is limited to a 11 mL blood draw in addition to the routine-care blood sample drawn from the same venipuncture, and a POC D-dimer test using capillary blood drawn from a finger prick.
For each different POC device, 70 patients will undergo additional testing, which amounts to 5 x 70= 350 patients in total.
Inclusion period will consist of 2 months at 10 puncture posts (2 puncture posts per hospital site) with a follow-up of 3 months.
The additional diagnostic value of four biomarkers (CRP, Procalcitonin, TAT complex and factor VIII) will be evaluated.
Patient burden and safety.
Burden for the patient is limited, for additional blood will be drawn from the same needle as being for the routine D-dimer test. The finger prick for POC testing is complementary and unavoidable, since for safety validation purposes material used for routine tests drawn from a venipuncture has to come from the same origin as the capillary blood used for POC testing. Thus, left over plasma cannot used for this purpose.

Note:This studie is a continuation of the EVA study; Netherlands Trial Register NL5974

Doel van het onderzoek

N/A

Onderzoeksopzet

6 months

Onderzoeksproduct en/of interventie

A single finger prick for capillary whole blood samples (<50 microlitres and for the regular blood sample for the requested D-dimer test, 11 ml of nasal blood is taken from the same needle for the study). So no extra venipuncture takes place.

Contactpersonen

Publiek

Jeroen Bosch Ziekenhuis
Ron Kusters

073-5532764

Wetenschappelijk

Jeroen Bosch Ziekenhuis
Ron Kusters

073-5532764

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with suspected Venous TromboEmbolism, in whom the GP orders a D-dimer test.
- Life expectancy more than 3 months.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Age below 18 year; anticoagulant treatment (vitamin K, NOAC, low molecular-weight heparin) for other causes than VTE: pregnancy or a life expectancy less than three months. Unwilling to practicipate in this study

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:	06-11-2020
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	28-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55145
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9154
CCMO	NL71809.028.19
OMON	NL-OMON55145

Resultaten

Samenvatting resultaten
N/A