Evaluation of biomarkers in VTE study with capillary blood sample; the EVA-II study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON55145

Source
ToetsingOnline

Brief title
EVA-II

Condition

- Embolism and thrombosis

Synonym
pulmonary embolism, venous thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Aksa Medical, Udenhout, The Netherlands,Axon Lab B.V., Zaltbommel, The Netherlands,Boditech Med Inc. Gangwong-do.

Republic of Korea,Het onderzoek wordt door de verrichter (JBZ) en drie sponsoren.,LumiraDx, Alloa, United Kingdom Ltd,Mediphos, Renkum, The Netherlands

Intervention

Keyword: D-dimer, General practice, Point-of-Care, Venous Thrombo Embolism

Outcome measures

Primary outcome

D-dimer result

Secondary outcome

Clinical outcom of VTE diagnosis

Study description

Background summary

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are two manifestations of Venous Thrombo-Embolism (VTE), is the third most common cause of cardiovascular death, after myocardial infarction and stroke, and has an annual incidence rate of about 1 per 1000 person-years in general population. Rapid diagnosis and treatment of VTE is important to the restrict disease progression and to lower the risk of fatal events.
The GP cannot trust on patient history, symptoms and signs for diagnosis, for signs and symptoms can be non-specific and frequently nearly absent, e.g. mimicking a simple leg or respiratory tract infection.
Therefore, the use of a Clinical Decision Rule (CDR) score combined with a D-dimer test in primary care is recommended. However, referral for imaging in a hospital setting is only recommended for those with a high CDR score, as well as those with a positive D-dimer test (regardless of the CDR-score). This approach is validated as a safe diagnostic strategy in suspected patients to refrain from referring nearly half of the patients and is written in current guidelines.
Very recently, novel Point-of-Care test devices have been introduced using a blood sample from a finger prick enabling appropriate use in GP practice. An additional advantage is that different frequently-ordered tests in primary care can be carried out on the same device (CRP, HbA1c etc).

Plasma samples of five devices under study have already been compared with a routine laboratory assay, STA-R Max, by the members of our study group (the EVA

study). Results of POC measurements have been shown to be comparable with the routine laboratory results. Before these devices can be introduced for usage in GP practice, validation of the sensitive D-dimer test using whole blood drawn by a finger prick procedure in primary care setting is needed.

Study objective

The primary objective of this study is an analytic validation of D-dimer tests with capillary whole blood of five different, recently introduced POC laboratory devices compared with a central routine lab D-dimer assay. Secondary objective is a clinical validation according to VTE diagnosis, as a Gold Standard is lacking for D-dimer measurement.

Study design

Prospective cohort study in patients suspected of having a VTE who are referred to a 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 anonymized 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 laboratories with a follow-up of 3 months.

Intervention

There is a minimal burden and risk for patients participating in the study, as the only intervention is to take an additional blood sample of 11 mL from the same venipuncture as a regular D-dimer test. Patient management will be completely guided by care as usual and current guidelines under responsibility of the treating physician.

Study burden and risks

Het kost de patiënt 20 minutes extra tijd en het risico bij een capillaire bloedafname is nihiel.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

Exclusion criteria are age below 18; 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 participate in this study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2020
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-06-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-11-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-06-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26166
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71809.028.19
OMON	NL-OMON26166