Urine prothrombin fragments (F1+2) as a diagnostic tool for arterial and venous thrombosis

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Primary objective: To investigate whether urine prothrombin fragments are increased in individuals suffering from VTE (i.e. PE or DVT) or a myocardial infarction compared to healthy matched controls.Secondary objective: to investigate whether...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34836

Source
ToetsingOnline

Brief title
The UPF study

Condition

- Other condition
- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arterial and venous thrombosus, deep vein thrombosus, myocardial infarction, pulmonary embolism, thrombosus

Health condition

bloedstolling, veneuze trombo embolien

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arterial thrombosis, diagnosis, urine prothrombin fragments, venous thrombosis

Outcome measures

Primary outcome

Urine F1+2 levels

Secondary outcome

Increased levels of urine F1+2 coincide with increased plasma levels of ddimer

and F1+2 in case of VTE and troponine T, CKMB, d-dimer and F1+2 in plasma

samples in patients with MI.

Study description

Background summary

The diagnosis of a thrombotic event, either an arterial or venous thrombosis, is often made in the event of a high clinical probability in combination with positive results of blood tests and imaging techniques which confirm the clinical suspicion.1-3
Individuals in whom thrombotic events are suspected immediately face invasive diagnostic tests to exclude and/ or confirm the possibility of thrombotic events.
However if a diagnostic tool could be developed to exclude thrombotic events in a relatively less invasive, inexpensive and patient friendly manner, both the patient as well as the national health care system could potentially benefit.
Furthermore urine testing (especially 24 hour measurements) to date have proven to have more diagnostic accuracy compared to plasma samples which tend to fluctuate in time (e.g endocrine parameters).4
To date thrombin generation markers, particularly ddimer, are routinely used as

part of the work-up of venous thrombo-embolism (VTE). Previously these markers were also shown to reliably predict the risk of both myocardial infarction (MI) and stroke. 5,6
Recently levels of prothrombin fragments, F1+2 were assessed in urine samples of patients who had undergone a total hip replacement surgery. Blood sampling took place prior to surgery and 3 days after the surgery. Increased urine F1+2 levels, were seen in patients who postoperatively suffered from deep vein thrombosis, whereas low levels of F1+2 were seen in individuals who suffered from bleeding complications after surgery. 7
Urine prothrombin fragments, like plasma prothrombin fragments, reflect the presence of thrombin generation, and could potentially replace blood sampling in patients with a suspicion of thrombotic events. Since Prothrombin is a marker of thrombin generation and is increased in the event of thrombotic events. Since prothrombin fragments F1+2 are excreted in the urine they can reliably be measured in a urine sample.
We hypothesize that prothrombin fragments in urine can be used to exclude thrombotic events in patients suspected of venous or arterial thrombotic events

Study objective

Primary objective: To investigate whether urine prothrombin fragments are increased in individuals suffering from VTE (i.e. PE or DVT) or a myocardial infarction compared to healthy matched controls.
Secondary objective: to investigate whether increased levels of urine F1+2 coincide with increased plasma levels of d-dimer and F1+2 in case of VTE and increased levels of troponine T, CKMB, d-dimer and F1+2 in plasma samples in case of MI.

Study design

This study has a cross-sectional design and will include 20 patients, aged 18 years and older with an objectively proven diagnosis of VTE (DVT or PE) and 20 patients with objectified diagnosis of MI. Furthermore 20 healthy volunteers will serve as control subjects. The patients will be enrolled at the department of vascular medicine of the Academic Medical Centre and the departments of Internal medicine and Cardiology of the Slotervaart Hospital in Amsterdam after informed consent has been obtained.
A urine sample will be obtained within 48 hours after the diagnosis has been made in which urine levels of microalbimun and creatinin as well as urine d-dimer and F1+2 levels will be determined. Simultaneously a blood sample will be obtained also within 48 hours after diagnosis has been made in which the d-dimer, and F1+2 levels will be determined. All other medical procedures such as imaging, blood sampling and treatment will be performed according to routine medical care.
The duration of the study be approximately 1 year or until a sufficient amount of participants has been reached.

Study burden and risks

The study does not carry much risk, the only burden may be time consumption which is in proportion to the potential value of the study for the researchers. No personal benefit can be obtained by participants of the study.

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

Males and females, aged 18 years and older with an objectively confirmed venous thrombo-embolism, either DVT or PE (by means of ultrasonography, computerized tomography or ventilation perfusion scanning) and an objectively confirmed diagnosis of

myocardial infarction (by means of elevated cardiac enzymes or abnormal elecocardiogram.

Exclusion criteria

Since this is a pilot study, there are no exclusion criteria.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL31889.018.10