thrombin generation in plasma, the predictive value of endogenous thrombin generation (ETG)in relation to hypercoagulability and bleedingrisk

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Assessing hereditary and aquired determinants of ETP. Evaluating the use of ETP as predictive stand alone test for recurrent DVT and bleeding complications due to anticoagulation therapy in comparisson with the current prediction methods.

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

Summary

ID

NL-OMON33539

Source
ToetsingOnline

Brief title
thrombin generation in plasma

Condition

- Other condition
- Blood and lymphatic system disorders congenital

Synonym
coagulation

Health condition

hypercoagulabiliteit

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bleedingrisk, endogenous thrombin generation, hypercoagulability, predictive value

Outcome measures

Primary outcome

Assessing the relation between outcomes of ETP (lag time, time to peak, area

under the curve) and prevalence of bleedingcomplications and recurrent

thrombosis.

Secondary outcome

Difference in genetic profile in relation to bleedingcomplications and or

recurrent thrombosis. (determinants of ETP)

Study description

Background summary

There is still much to be learned about the optimal duration of anticoagulation therapy and predictive risk factors for recurrent thrombosis and bleeding. At this moment in time screening for thrombophilia gives insight in the origin of thrombosis only in about 50% of the cases. Currently prediction of risk for recurrence is based on patient history, clinical presentation, findings on ultrasonography and laboratory tests. The levels of factor VIII and D-dimer fragments in the blood are currently used as more or less predictive laboratory test. Also residual thrombosis is taken into account. In stead of looking at two seperate coagulation parameters, a more general assessment of the coagulationsystem can be provided by the endogenous thrombin generation potential. (ETP) With this test it is possible to establish

within 1 hour whether or not a patient has a prothrombotic tendency. All known genetic factors such as factor V Leiden mutation, protthrombin mutation, antithrombin deficiency, protein C and or S deficiency as well as aquired factors such as lupus anticoagulans and anticardiolipin antibodies can be detected. Also factors involved in an enhanced bleeding tendency such as factor VIII deficiency and anti factor VIII antibodies. All these factors can be observed in their interactive status

Study objective

Assessing hereditary and aquired determinants of ETP. Evaluating the use of ETP as predictive stand alone test for recurrent DVT and bleeding complications due to anticoagulation therapy in comparisson with the current prediction methods.

Study design

It is a prospective cohort study in an academic hospital setting

Study burden and risks

Thete is no risk associated with participation. There is no direct benefit for the patient.

Contacts

Public
Selecteer

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NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

all mentaly capacitated consecutive patients presented in the outpatient clinic for follow up of objectively confirmed venous thrombosis over the age of 18 years.

Exclusion criteria

age under 18 year, mental incapacity

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):	31-01-2007
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	09-01-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-10-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL15489.068.06