The influence of the proteins of the contact activation system on thrombus formation under different flow-conditions in blood

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We will study the effects of the proteins of the contact activation system in thrombus formation, embolization and degradation in several coagulation assays.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON39076

Source
ToetsingOnline

Brief title
Thrombus formation under different flow-conditions

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Embolism and thrombosis

Synonym
arterial thrombosis, increased coagulation

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

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

Intervention

Keyword: contact activation system, flow chamber experiments, thrombus formation

Outcome measures

Primary outcome

Our main study endpoint is the ex vivo formation of thrombi in several coagulation assays. We hypothesize that thrombi formed from blood of patients deficient in FXII or FXI are less stable than those formed from blood from controls.

Secondary outcome

not applicable

Study description

Background summary

Cardiovascular diseases are important causes of morbidity and mortality in the industrialized world. Clinical studies indicate an important role for the proteins of the contact activation system (coagulation factor XII (FXII), FXI, prekallikrein and high molecular weight kininogen (HMWK)) on the risk of cardiovascular disease. There is substantial evidence from mouse studies that FXII and FXI participate in the formation and stability of thrombi and in vitro studies showed that collagen is able to activate FXII and hereby stimulate thrombin formation and potentiate the formation of platelet-fibrin thrombi. We want to determine the role of the proteins of the contact activation system in platelet mediated thrombus formation in human blood.

Study objective

We will study the effects of the proteins of the contact activation system in thrombus formation, embolization and degradation in several coagulation assays.

Study design

Blood will be collected from human volunteers via a venipuncture in the forearm. Each volunteer will donate maximally four times 30 ml of blood over a period of two days. This blood is used incoagulation assays. We need fresh whole blood because platelets are viable for four hours. After this time, new blood is needed.

Study burden and risks

Blood will be drawn via a venipuncture in the forearm, maximally four times during two days. Blood collection takes place at the academic hospital in Maastricht. Each venipuncture is associated with a bleeding risk at the site of puncture. FXI deficiency is associated with a mild bleeding tendency, however the risk of bleeding after venipuncture is minimal. Deficiency in FXII, prekallikrein or HMWK is not associated with a bleeding diathesis and therefore the bleeding risk is equal to the risk in the control population.

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

• Age: >= 18 years
• Deficiency in coagulation factor XII, coagulation factor XI, prekallikrein or high molecular weight kininogen (patients)

Exclusion criteria

(Other) Coagulation defects
Symptoms of active disease
Use of anti-platelet drugs
Use of aspirin / ascal

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-05-2011
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-07-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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
ClinicalTrials.gov	NCT01114074
CCMO	NL31014.068.10