Effect of anticoagulants or procoagulants on thrombin generation in PPP, PRP and whole blood

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

Summary

ID

NL-OMON39676

Source
ToetsingOnline

Brief title
Effect of anti- or procoagulants on thrombin generation

Condition

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

Synonym
bleeding, coagulation disorder, coagulopathy, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Synapse BV

Intervention

Keyword: anticoagulants, procoagulants, thrombin generation

Outcome measures

Primary outcome

Thrombin generation will be determined in PPP, PRP and whole blood with or without flow. The data that will be collected through these experiments will be analysed with the use of 4 parameters: endogenous thrombin potential (ETP), peak height, time to peak and lag time. The thrombin generation experiments will be performed in the absence and presence of anticoagulant agents or agents that will possibly affect thrombin formation. If necessary, clotting factor determinations will be performed on the stored PPP, these can be antigen determinations or functional determinations.

Control experiments need to be carried out in order to check the quality of the blood/plasma by using the standard procedures of the lab: e.g. cell count, flow cytometry, aggregometry, clotting*

Secondary outcome

NA

Study description

Background summary

Thrombin generation is becoming an increasingly important tool to measure the variables of the clotting system. We can not only use thrombin generation testing to evaluate the coagulation system of a person, but we can also add different agents to the test in order to evaluate the effect on an individual*s

plasma. The effect of anticoagulant and procoagulant agents has already been investigated by using Calibrated Automated Thrombography (CAT) in plasma. However, Synapse bv also developed a method for measuring thrombin generation in whole blood and a method for measuring thrombin generation under flow. Consequently, we want to compare the effect of different anticoagulant and procoagulant agents in platelet poor, platelet rich plasma (PPP, PRP) and whole blood.

Study objective

The main objective is to determine the effect of different anticoagulant and procoagulant agents on thrombin generation in whole blood and compare it to the effect on thrombin generation in PPP and PRP at different tissue factor concentrations. In other words, we want to validate the whole blood CAT assay by comparing it to the CAT in plasma. We would also like to measure thrombin generation and viscosity under flow conditions resembling shear rates in in vivo venous and arterial blood flow.

The secondary objective is to determine the inter-individual variability in response to the different agents.

Study design

This study is of invasive design. Yet, the impact will be minimal for the subjects. A venipuncture will be performed in healthy volunteers (male and female) between the ages of 18 and 65 years. Before blood collection an informed consent form will be signed. An estimated 175 blood donations will be needed over a period of 4 years. A donor will be asked to participate in the study one time, which means that he/she will undergo only one blood draw.

The study aims to compare thrombin generation with or without agents with an anticoagulant or procoagulant effect. This will be done in PPP, PRP and whole blood of healthy donors with or without flow. In this way we can compare the effect of agents in whole blood to that in PPP and PRP. The duration of the study for each individual subject will be limited to a few minutes.

We would like to add different anticoagulant or procoagulant agents to the blood and plasma of each subject, though it is not possible to add all agents which we want to investigate. For this reason we opt to add 3 agents to the blood/plasma of one subject. This means that we need three tubes or 30 ml of citrated blood per subject, so 27 ml of blood will be collected into three tubes which contain 1 ml of citrate solution each.

Study burden and risks

Venipunctures will be performed by experienced co-workers. Nevertheless, blood

sampling causes local bruising and incidentally a hematoma may occur. Occasionally, a donor might feel dizzy or can faint during or after the blood sampling. There is also a small possibility that an infection occurs. All possible precautions will be taken to avoid manifestation of these risks. There will be no direct benefit to the subjects.

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

Healthy men and women between 18 and 65 years

Exclusion criteria

- Use of a drug that interferes with coagulation (e.g. oral anticoagulants, oral contraceptives, oral antiplatelet drugs).
- A history of bleeding or thrombosis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	175
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-03-2013
Application type:	First submission
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	NL42699.068.12