The importance of platelet derived tissue factor pathway inhibitor in coagulation

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

Summary

ID

NL-OMON37601

Source
ToetsingOnline

Brief title
Platelet TFPI and coagulation

Condition

- Other condition
- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Coronary artery disorders

Synonym
coagulation thrombosis

Health condition

gezonde proefpersonen, fysiologie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Nederlandse hartstichting grant numer 2007b138

Intervention

Keyword: healthy volunteers, platelets, TFPI, thrombin generation

Outcome measures

Primary outcome

The main study parameters are the peak height of the thrombin generation curve in plasma obtained from non activated platelet rich plasma (PRP) compared with the peak height of the thrombin generation curve in plasma obtained from activated PRP by T different agonists. Thrombin generation will be determined under different assay conditions:

triggered with low and hihg TF concentrations

in the absence and presence of anti-TFPI antibodies and anti protein S antibodies. In 8 healhty volunteers different available TFPI tests will be performed.

Secondary outcome

TFPI elisa and protein S elisa in plasma obtained from non activated platelet rich plasma (PRP) compared with the peak height of the thrombin generation curve in plasma obtained from activated PRP activated by platelet agnostists.

western blot, flow cytometry, activity assays.

Study description

Background summary

Tissue factor pathway inhibitor (TFPI) is a natural and potent anticoagulant protein. It is a kuntiz type serine protease and has a acidic N terminal region, three tandemly ranked kunitz-domains and a basic C-terminal region. The protein has a plamsa concentration of 2.5nM en only 10% of plasma TFPI is the free full length form, which is recognized as the active anticoagulatn form of the protein. About 5-10% of plasma TFPI is located within platelets. However the role of platelet TFPI in coagulation is not known.

Study objective

The gaol of the present study is to determine the role of platelet derived TFPI on coagulation in healthy male subjects (n=10) and in healthy female subjects either using (n=10) or not using oral contraceptives (n=10). Additionally 8 healthy volunteers (M/F, age 18-55 years olf) will be included. in total 38 healthy volunteers will be included in the study. Exclusion criteria are the use of anticoagulant agents or thrombocytaggregation inhibitors/NSAIDs in the two weeks prior to the study.

Study design

It is a invasive observational study. The burden for the volunteers is low. One blood sample will be taken on one single occasion. Subjects included in the study are healthy male and female subjects aged between 18 aan 55 years old. Subjects will be recruted from the hospital and unversity employees. Written informed consent will be obtained from all participant before the blood collection. In total 31.5 mL of blood wil be taken: 4.5mL of EDTA blood for whole blood count. 18mL citrated blood for activation of platelets by platelet agnosists, and 9 mL of citrated blood as a control (a buffer will be added as a control).

Study burden and risks

The risks involved in this study are equal to risk associated with a vein puncture. These are small hematomas at the site of puncture and bruising and will dissapear spontaneously over a couple of days. Fainting might results during blood collection. Therefore samples will be obtained in the supine position.

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 18-55 years old
written informed consent

Exclusion criteria

use of anticoagulant agents (such as heparin, vitamin K antagonists)
use of aspirine, clopidogrel or non steroidal anti-inflammatory drugs within 2 weeks prior to the 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):	01-02-2012
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO Date:	30-12-2011
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	12-09-2012
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	NL38317.068.11