Ex vivo clot lysis measurements in blood samples of healthy volunteers.

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

Summary

ID

NL-OMON36990

Source
ToetsingOnline

Brief title
ROTEM-LYSIS study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
Hyperfibrinolyse, increased bloodclot breakdown

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fibrinolysis, Hyperfibrinolysis, Platelet aggregation, Thromboelastometry

Outcome measures

Primary outcome

The main study parameter/endpoint is the Lysis onset time (time to the start of hyperfibrinolysis)

Secondary outcome

Secondary study parameters/endpoints are: Blood coagulation (INTEM, EXTEM, APTEM and FIBTEM) and fibrinolytic parameters (Maximum lysis (ML), Lysis Index at 30 and 45 minutes after clot formation (LI30, LI45) and lysis time (LT) and platelet aggregation index

Study description

Background summary

Thromboelastometry is a point of care testing device that determines the viscoelastic properties of clot formation in whole blood. It is currently the only clinically device that is able to measure clot lysis. A previous study by our group investigated the incidence and severity of hyperfibrinolysis in patients after out-of-hospital cardiac arrest. Using thromboelastometry, we found that approximately 50% of these patients had hyperfibrinolysis. There is however only limited research available using thromboelastometry for the diagnosis of hyperfibrinolysis, and there is no consensus on witch parameter is suitable to determine the degree of hyperfibrinolysis.
Schöchl et al. used a categorical scale dividing them into fulminant, intermediate and late hyperfibrinolysis based on the time to reach complete lysis. A previous study performed by Nielsen et al. investigated the relation between thromboelastography parameters and increasing tPA concentrations in blood from healthy volunteers, and they concluded that thromboelastography could be an appropriate laboratory and clinical tool for quantifying fibrinolysis.
Recent findings by our group showed that the lysis onset time (LOT) shows a linear relation with markers of hypoperfusion in patients after out of hospital

cardiac arrest. Our findings suggested that the lysis onset time is a more accurate marker for the severity of hyperfibrinolysis than the maximum lysis. Whether the LOT is indeed a good measure of hyperfibrinolysis, and linearly related to tPA concentrations, has however never been investigated. Moreover, A recent study by Panes et al. suggested that platelets have a pro-fibrinolytic function. They showed a faster clot lysis in platelet-rich clots compared to platelet-poor clots after addition of tranexamic acid that was absent platelet-free plasma.

Study objective

In the present ex vivo study we aim to determine whether thromboelastometry parameters, in particular the lysis onset time (LOT), are appropriate to determine and quantify the degree of hyperfibrinolysis. Furthermore, we will study the association of increasing tPA concentrations with the lysis onset time and platelet function.

Study design

This is a prospective, single center, observational study in blood samples of healthy volunteers and will be performed in the department of Anesthesiology of the VUmc in Amsterdam.

Study burden and risks

The burden associated with participation is minimal being limited to 10 minutes required for a single blood withdrawl. The risk is equal to the risk of venous blood withdrawl and is limited to a hematoma at the site of puncture.

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 volunteers aged 18-40 years.

Exclusion criteria

anticoagulant or antiplatelet medication, pregnancy, history of hematologic disorders, history of deep venous thrombosis of pulmonary embolism

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2013
Enrollment:	15

Type:	Actual

Ethics review

Approved WMO Date:	22-08-2012
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	NL40763.029.12