Influence of endothelial cells on coagulation and fibrinolysis measured by thromboelastography

Published: 10-01-2012
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The purpose of the study is to investigate the effect of endothelial cells in TEG-cups compared to plain (no endothelial cells) cups on coagulation and fibrinolysis.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35868

Source
ToetsingOnline

Brief title
ECCO 1

Condition

- Other condition

Synonym
fibrinolysis and coagulation

Health condition

stolling

Research involving
Human

Sponsors and support

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

Intervention

Keyword: coagulation, endothelial cells, fibrinolysis, thromboelastography

Outcome measures

Primary outcome

Endothelial cell coated TEG cups are compared to plain TEG cups (not endothelial coated) by thromboelastographic variables: reaction time (r), kinetic time (k), α angle (α), maximal amplitude (ma) and the extension of fibrinolysis after 30 minutes (Ly30).

Secondary outcome

NP

Study description

Background summary

Thromboelastography (TEG) is used to assess hemostasis in whole blood1. It is a dynamic test depicting the initiating, the structural characteristics and stability of the formed clot. Routine laboratory tests are, in contrast to TEG, performed on plasma only and provide no information about interactions of blood cells, pro- and anticoagulants, and pro- and antifibrinolytic factors, essential in the clotting process.
However, the TEG test results do not cover all elements involved in hemostasis. Endothelial cells (EC) form the luminal vascular surface play a central role in the regulation of coagulation and fibrinolysis.
In coagulation EC regulates binding sites for anti- and procoagulant factors on the cell surface. EC maintain the blood fluidity by promoting anticoagulant pathways including the protein C/S pathway. Tumor necrosis factor (TNF) suppresses thrombomodulin binding on EC and induces expression of tissue factor resulting in a state to favour clot formation.
In fibrinolysis EC express both types of plasminogen activators, the

urokinase-type PA and the the tissue-type plasminogen activator, as well as their inhibitor plasminogen activator inhibitor type (PAI-I). Stimulation or inhibition of these activators may result in a hypo- or hyper- fibrinolysis.

Test results of the TEG are missing the important influence of the endothelial cells simply because the test is performed in a plastic cup without an endothelial layer. This shortcoming may be resolved by introducing endothelial cells in the TEG test-cup.

Human Umbilical vein endothelial Cells (HUVEC) are isolated from human umbilical vein. These cells are commonly used for physiological and pharmacological investigations including blood coagulation2 and fibrinolysis3. It is possible in the laboratory of the UMCG (endotheelcel & vasculaire drug targering) to cover the TEG-cups with HUVEC. This technique has not been described in the literature and hence, the effect of EC-coated TEG-cups compared to the plain TEG-cups on hemostasis has not been studied before.

Study objective

The purpose of the study is to investigate the effect of endothelial cells in TEG-cups compared to plain (no endothelial cells) cups on coagulation and fibrinolysis.

Study design

clinical observational mono-center study

Study burden and risks

From healthy volunteers 5 ml of venous blood is collected. It is unlikely that subjects will experience any physical or psychological discomfort from this blood sampling.

Contacts

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Selecteer

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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

Adult: 18 - 55 years old

Exclusion criteria

Hemostatic disorders
use of antiocoagulantia

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved

Date:	10-01-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL35793.042.11