Whole blood thrombin generation test- a clinical validation

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25031

Source
Nationaal Trial Register

Health condition

non-cardiac surgery (niet cardiale chirurgie), bleeding (bloeding), haemostasis (haemostase)

Sponsors and support

Primary sponsor: Maastricht University Medical Center and
Synapse b.v. (CARIM)
Oxfordlaan 70
6229EV Maastricht
Source(s) of monetary or material Support: Synapse b.v. (CARIM)
Oxfordlaan 70
6229EV Maastricht

Intervention

Outcome measures

Primary outcome

Whole blood measeurement before and after treatment compared to standard plasma thrombin generation

Secondary outcome

parameters of clinical bleeding (transfusion after the second test, fluid substitution)

Study description

Background summary

Rationale: The Calibrated Automated Thrombogram (CAT) assay is nowadays a very helpful tool to measure thrombin generation (TG) in the field of thrombosis and haemostasis research. Unfortunately up to now, it was only possible to perform this assay in platelet rich and poor plasma, but not in whole blood due to technical issues. We were able to overcome these problems and to adapt the CAT assay to make it able of measuring TG in a small volume of whole blood. The advantages are that whole blood is more physiological than plasma and that it can be used directly, reducing not only the time to perform the assay, but also the experimental errors that can occur.

Objective: Our primary objective is to validate our newly developed whole blood TG assay. In order to do this we want to compare and correlate the outcome of the TG assay in whole blood with TG in plasma, and also with the ROTEM, the scanning electron microscopy (SEM) and the routine coagulation tests that are performed in the hospital. Our secondary objective is to compare the results from all tests before and after transfusion of blood products and/or factor concentrates to check whether the improvement in the haemostatic function of the patient can also be detected with our newly developed whole blood TG assay.

Study design: This is a observational, comparative study between the results of the routine coagulation tests that are performed in the hospital, the ROTEM results, the SEM analysis, the results from TG in plasma with our newly developed TG assay in whole blood.

Study population: Patients above the age of 18 that are suffering from a bleeding and are transfused with blood products and/or factor concentrates during/after major surgery.

Main study parameters/endpoints: We are going to compare and correlate all the TG parameters (peak height, endogenous thrombin potential, lagtime, time-to-peak, velocity index) in plasma and whole blood with the SEM pictures (density and thickness of the fibrin network), ROTEM and the routine coagulation tests of the hospital (activated partial thromboplastin time, prothrombin time, INR, fibrinogen concentration, haematocrit, platelet count).

Study objective

Whole blood thrombin generation generates reliable results which are comparable to plasma thrombin generation.

Study design

Samples are taken before and after transfusion.

Intervention

Patients with controlled bleeding due to non cardiac surgery will receive standard treatment with blood products according to local protocols.

Contacts

Public
dept of anesthesiology
MUMC+
P.Debeyelaan 25

M.D. Lancé
Maastricht 6202 AZ
The Netherlands
Scientific
dept of anesthesiology
MUMC+
P.Debeyelaan 25

M.D. Lancé
Maastricht 6202 AZ
The Netherlands

Eligibility criteria

Inclusion criteria

Patients undergoing major surgery (major abdominal surgery, aorta aneurysms, major orthopaedic surgery) that have a greater chance to develop a bleeding will be asked to participate to our study. Patient inclusion will only occur when they are suffering from a bleeding during/after major surgery receiving a transfusion of blood products and/or factor concentrates.

Exclusion criteria

age below 18 years.

Patients with acute life-threatening bleeding.

Patients undergoing cardiothoracic or vascular surgery receiving heparintherapy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-11-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2013
Application type:	First submission

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
NTR-new	NL4018
NTR-old	NTR4261
Other	: METC 12-4-144
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A