Whole blood thrombin generation test- a clinical validation

Gepubliceerd: 08-11-2013 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25031

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University Medical Center and
Synapse b.v. (CARIM)
Oxfordlaan 70
6229EV Maastricht
Overige ondersteuning: Synapse b.v. (CARIM)
Oxfordlaan 70
6229EV Maastricht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Whole blood measeurement before and after treatment compared to standard plasma

thrombin generation

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

Samples are taken before and after transfusion.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

dept of anesthesiology
MUMC+
P.Debeyelaan 25

M.D. Lancé
Maastricht 6202 AZ
The Netherlands

Wetenschappelijk

dept of anesthesiology
MUMC+
P.Debeyelaan 25

M.D. Lancé
Maastricht 6202 AZ
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

age below 18 years.

Patients with acute life-threatening bleeding.

Patients undergoing cardiothoracic or vascular surgery receiving heparintherapy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	11-11-2013
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4018
NTR-old	NTR4261
Ander register	: METC 12-4-144
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A