Validation of a new fibrinolysis assay for thrombelastometry on the ROTEM® device

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The aim of this study is to evaluate the effects of platelet transfusions on hemostatic parameters in thrombocytopenic hematology patients and to identify other determinants of hemostasis, which may contribute to clot formation and clot strength.

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

Samenvatting

ID

NL-OMON21605

Bron
NTR

Verkorte titel
The THROMBO-trial

Aandoening

Sepsis (with/without DIC), Liver impairment (Child-Pugh A/B/C), Patientgroups in which an altered hemostatic balance can be expected, like patients treated for hematological malignancies who have severe thrombocytopenia

Ondersteuning

Primaire sponsor: MUMC+
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Validation of a newly developed fibrinolysis assay on the ROTEM® device in multiple groups of patients with different pathological entities.

Toelichting onderzoek

Achtergrond van het onderzoek

Fibrinolysis measurement on the ROTEM® device
Monitoring of coagulation in massive bleeding patients is vital for decision making. The use of point of care devices, such as ROTEM® or TEG®, reduces the need of transfusion products during surgical operations [1]. Both devices give information of the formation of the fibrin clot and its strength and the lysis of the fibrin clot in whole blood, a original concept of Hartert [2]. In the ROTEM® device a elaborate set of activating reagents can be used to induce fibrin formation in different ways or to give specific information about different parts of the coagulation cascade [3]. One of the tests used is the APTEM test for fibrinolysis measurement. In this test the coagulation is triggered by adding tissue factor (TF) while fibrinolysis is blocked by adding aprotinin. The resulting cigar shaped figure is then compared to a blood sample triggered by only TF (EXTEM test) without any blocking agents. If (hyper)fibrinolysis is present the abnormally shaped cigar triggered by the EXTEM reagent, will be normalized in the APTEM triggered blood sample.
Fibrinolysis in massive bleeding patients
There is one downfall of the use of this APTEM versus EXTEM method: time. In massive bleeding time is crucial for the outcome of the patient. Classic aPTT and PT measurements are time consuming and do not give a good overall view on coagulation [4]. Both point of care devices (ROTEM® or TEG®, the ROTEM® counterpart) give a more better overview of coagulation in lesser time. After 10-15 minutes it is already possible to predict what the final fibrin clot formation will be using the A10 (amplitude after 10 minutes) [4]. Contrary fibrinolysis can only be seen after the maximum clot formation (MCF) has been reached. This can take up to or over 30 minutes. Using the euglobulin clotlysis time to measure fibrinolysis can take even three times longer. A reliable and valid method to quickly evaluate fibrinolysis and antifibrinolytic treatment effects in massive bleeding patients is unavailable.
Fibrinolysis in bleeding and thrombotic tendency diagnosis
In the past several research groups have studied fibrinolysis by inducing fibrinolysis on either device by various methods [3, 5-11]. Inducing fibrinolysis can potentially speed up the analysis time. Besides, by triggering fibrinolysis it may be possible to pick up subtle difference between groups, by tipping the hemostatic balance towards bleeding. For instance in hepatic disease the newly formed hemostatic balance is prone to either bleeding or clotting [12]. For ROTEM® no induced fibrinolysis assay in whole blood has thus far been validated for large groups of patients with different pathologies in which a altered hemostasis can be expected. A reliable and valid method to evaluate the hemostatic balance between

bleeding and thrombosis in patients is unavailable.

Doel van het onderzoek

The aim of this study is to evaluate the effects of platelet transfusions on hemostatic parameters in thrombocytopenic hematology patients and to identify other determinants of hemostasis, which may contribute to clot formation and clot strength.

Onderzoeksopzet

2021 analyss of NATEM ROTEM parameters in CIT patients
2019 analysis of TPA ROTEM parameters and the effect of platelet transfusion in CIT patients

Contactpersonen

Publiek

MUMC+
Floor Heubel-Moenen

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Wetenschappelijk

MUMC+
Floor Heubel-Moenen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The population consist of all in hospital adult (≥ 18 years old) patients at the Maastricht University Medical Centre. 20-30 patients of each group will be asked informed consent for blood withdrawal for this in vitro measurement on the ROTEM® device.
The population consist of the following patient groups:
- Sepsis (with/without DIC)
- Liver impairment (Child-Pugh A/B/C)

- Patientgroups in which an altered hemostatic balance can be expected, like patients treated for hematological malignancies who have severe thrombocytopenia

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

temperature >38,0˚C, sepsis, active bleeding, splenomegaly or use of anticoagulation medication.

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 gestart
(Verwachte) startdatum:	28-07-2021
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-07-2021
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	NL9645
Ander register	METC AzM/MUMC : METC114097

Resultaten