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

No registrations found.

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

Summary

ID

NL-OMON21605

Source
NTR

Brief title
The THROMBO-trial

Health condition

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

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Validation of a newly developed fibrinolysis assay on the ROTEM® device in multiple groups

of patients with different pathological entities.

Secondary outcome

Effects of platelet transfusion on fibrinolysis assays in chemotherapy induced thrombocytopenic patients

Study description

Background summary

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.

Study objective

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.

Study design

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

Contacts

Public
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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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:	Recruiting
Start date (anticipated):	28-07-2021
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-07-2021
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	NL9645
Other	METC AzM/MUMC : METC114097

Study results