ROTEM in critically ill patients at risk for DIC

No registrations found.

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

Summary

ID

NL-OMON22092

Source
Nationaal Trial Register

Brief title
TROPIC

Health condition

Disseminated intravascular coagulation

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Cut off values of parameters of coagulation profiles as determined by ROTEM (speed and degree of clot formation, degree of fibrinolysis) corresponding to an ISTH DIC score of ≥ 5 as the gold standard, DIC with bleeding, DIC with thrombotic events, bleeding and thrombotic events in critically ill patients at risk for DIC without an ISTH DIC diagnosis, and mortality.

Secondary outcome

Distinguish patients based upon ROTEM profiles that may benefit from timely anticoagulant strategies
Compare ROTEM profiles and other parameters of coagulation between patients who have DIC due to different clinical risk factors
Determine a critical fibrinogen to nucleosome ratio that corresponds to the development of DIC and thrombosis
Relate nucleosome levels to other markers of endothelial activation and coagulation
Determine specific clinical risk factors for bleeding and thrombosis in DIC

Study description

Background summary

Disseminated intravascular coagulation (DIC) is a devestating complication of critical illness and an independent predictor of organ failure and mortality. DIC is characterized by systemic vascular activation with ensuing consumption coagulopathy with microthrombi formation. Thereby, patients are at risk for both bleeding and thromboembolic events. However, specific risk factors for bleeding and thrombosis are unknown. Current diagnostics rely on conventional coagulation testing to calculate a DIC score. However, this score cannot predict the risk for thrombosis or bleeding and hence cannot discriminate which patients would benefit from an anticoagulant strategy. Rotational thromboelastometry (ROTEM) may have the potential to diagnose both DIC as well as predict risks of bleeding and thrombosis in patients at risk for DIC.

The aim of our study is twofold: 1) to measure ROTEM profiles in critically ill patients at risk for DIC to determine cut off values of ROTEM corresponding to the currently used International Society for Thrombosis and Haemostasis (ISTH) DIC scores, as well as to bleeding and thromboembolic events. 2) to measure damage associated molecular patterns (DAMPs) and other parameters of the DIC coagulation cascade to improve insight in the pathophysiology of DIC.

Study objective

ROTEM is able to detect DIC and predict which patients are at risk of bleeding or thrombosis. Furthermore, we hypothesize thromboembolic events due to DIC occur when fibrinogen drops below a certain value compared to DAMP levels.

Study design

Single blood draw between day 1 - 4 of ICU stay.

Contacts

Public
Amsterdam University Medical Center, University of Amsterdam
Romein Dujardin

0205666328
Scientific
Amsterdam University Medical Center, University of Amsterdam
Romein Dujardin

0205666328

Eligibility criteria

Inclusion criteria

- Critically ill patients ≥ 18 years of age with a clinical condition that is associated with a risk of developing DIC (e.g. severe infection, post-surgery severe infection, trauma, acute pancreatitis, tumors, hematologic malignancy).
- Platelet count < 150x10^9/L

Exclusion criteria

- No informed consent
- Active bleeding requiring transfusion
- No arterial catheter in situ
- Proven other cause of low platelet count (e.g. heparin induced thrombocytopenia)

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):	01-10-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-09-2020
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	NL8904
Other	METC AMC : METC 2020_089

Study results