ROTEM in critically ill patients at risk for DIC

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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.

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

Samenvatting

ID

NL-OMON22092

Bron
Nationaal Trial Register

Verkorte titel
TROPIC

Aandoening

Disseminated intravascular coagulation

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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:	01-10-2020
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:	16-09-2020
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	NL8904
Ander register	METC AMC : METC 2020_089

Resultaten