

# ROTEM in critically ill patients at risk for DIC

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22092

### Source

NTR

### 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  $\geq 5$  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 devastating 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

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### Scientific

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## Eligibility criteria

### Inclusion criteria

- Critically ill patients  $\geq 18$  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  $< 150 \times 10^9/L$

### 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