rotational ThROmboelastometry in Patients at risk for disseminated Intravascular Coagulation*

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational non invasive

Summary

ID

NL-OMON52932

Source
ToetsingOnline

Brief title
TROPIC study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
DIS, verhoogde stollingsneiging

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: FP7 EU funding

Intervention

Keyword: bleeding, DIC, histones, thrombosis

Outcome measures

Primary outcome

ROTEM value corresponding to DIC

Secondary outcome

level of damage molecules and other proteins that contribute to the

pathophysiology of DIC

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. Thereby, patients are at risk for both bleeding and thromboembolic events. Current diagnostics do not predict the risk for thrombosis or bleeding and hence cannot discriminate which patients would benefit or harm from an anticoagulant strategy.

Rotational thromboelastometry (ROTEM) can both detect a hypo- and hypercoagulable profile and therefore may have the potential to diagnose both DIC as well as predict risks of bleeding an thrombosis in patients at risk for DIC. Besides the limited knowledge on individual risk factors for bleeding or thrombosis, the exact pathophysiology of DIC also remains unknown. Experimental data suggest that fibrinogen may protect against DIC by binding histones, but clinical data are scarce.

Study objective

The aim of this study is twofold: 1) to measure ROTEM profiles in 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 histones and other parameters of the DIC coagulation cascade to improve insight

in the pathophysiology

Study design

Multi center observational cohort study

Study burden and risks

The burden and risk associated with participation are negligible. A single blood sample will be obtained from the arterial line whichis already in place

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients admitted to the ICU who have a risk factor for DIC (infection, obstetric complication, malignancy, trauma, liver disease, pancreatitis)

Exclusion criteria

no informed consent
active bleeding
no arterial catheter in place

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2021
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
CCMO	NL73336.018.20