Peroperatieve researchstudy with de ROTEM machine to hemostase of patients during aorta abdominalis aneurysm operation.

Published: 31-10-2013
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Objective of the study:Investigating with use of the classical coagulation tests on one hand and with the ROTEM on the other hand what is exactly becoming disturbed in the coagulaton because of bleeding during surgery of the aorta abdominalis,...

Ethical review	Not approved
Status	Will not start
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational non invasive

Summary

ID

NL-OMON37252

Source
ToetsingOnline

Brief title
ROTEM study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
Haemostasis

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis

Source(s) of monetary or material Support: ROTEM Bedrijf;ondersteund ook door CSL Behring BV

Intervention

Keyword: Aorta abdominalis, APPT, INR, Tromboelastography

Outcome measures

Primary outcome

Correlation between ROTEM and clotting parameters values, blood loss and

bloedtransfusie

Secondary outcome

IC recording, infections, ventilatory and circulatory support

Study description

Background summary

Background of the study:
Because nowadays it is common practice in bleeding patients first to infuse crystalloid and colloid fluids before starting transfusion of blood or blood products, a dilutional coagulopathy can easily develop. It is also common practice to transfuse separate blood components instead of full blood. Trasnfusion of blood components in the wrong ratio may easily maintain a coagulopathy and hence contribute to blood loss. The classical coaguloation tests such as the APTT, PT and INR measure after activation only the activity of some of the coagulation factors present in the plasma, without paying any attention to the contribution of cellular components of blood to the coagulation. In these tests is only measured the number of seconds that it takes before the coagulation is initiated. The propagation fase, the polymerization of fibrinogen, the interaction between activated platelets and fibrinogen, the quality of the formed clot and whether the fibrinolysis is activated enough to break down the clot is completely overlooked by these tests. Thromboelastography/thromboelastometry on the other hand, performed in full blood including the cellular components measures the initiation phase, the propagation phase, the quality of the formed clot and whether the formed clot is broken down by the fibrinolysis.

Study objective

Objective of the study:
Investigating with use of the classical coagulation tests on one hand and with the ROTEM on the other hand what is exactly becoming disturbed in the coagulaton because of bleeding during surgery of the aorta abdominalis, measuring the effect on the coagulation of diluting the blood with different infusion fluids, investigating the correlation between the classical coagulation tests and the coagulation parameters measured with the ROTEM and the correlation between the coagulation tests and perioperative blood loss.

Study design

Descriptive research on coagulation in patients during surgery of the aorta abdominalis.

Study burden and risks

Not apply

Contacts

Public
Maasstadziekenhuis

Maasstadweg 21
rotterdam 3079 DZ
NL
Scientific
Maasstadziekenhuis

Maasstadweg 21
rotterdam 3079 DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

aneurysm aorta abdominalis

Exclusion criteria

None

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Not approved

Date:	31-10-2013
Application type:	First submission

Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL43066.101.12