

POC whole blood thrombin generation

No registrations found.

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

Summary

ID

NL-OMON22346

Source

Nationaal Trial Register

Health condition

cardiac surgery (hart chirurgie), thrombin generation (trombin vorming), coagulation (stolling)

Sponsors and support

Primary sponsor: Maastricht University Medical Center

Source(s) of monetary or material Support: Synapse b.v.

Intervention

Outcome measures

Primary outcome

Whole blood thrombin generation results compared to automated plasma thrombin generation results

Secondary outcome

1. lab results (ROTEM, whole blood TG, classic coagulation tests)
2. clinical association with bleeding (amount of blood loss, fluid infusion and use of blood products)

Study description

Background summary

Post cardiac surgery patients may suffer from bleeding. For optimal tailoring hemostatic therapy thromboelastometry (ROTEM) is frequently used. Thrombin generation measurement could improve treatment. However this technique still is workintensive and time consuming. Whole blood thrombin generation might deliver the comparable results within a shorter period of time. It will be tested and compared to plasma thrombin generation, thromboelastometry and clinical parameters.

Study objective

Whole blood thrombin generation measurement is comparable to plasma thrombin generation in clinical setting.

Study design

measurement before and after surgery upon arrival on the ICU

Intervention

observational study investigating coagulation capacity by the means of whole blood thrombin generation.

Contacts

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Eligibility criteria

Inclusion criteria

All consecutive patients after cardiac surgery during a period of 18 weeks.

Exclusion criteria

age under 18 yrs.
known coagulation disorder.

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:	Pending
Start date (anticipated):	14-10-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date: 08-10-2013
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	NL4091
NTR-old	NTR4237
Other	: METC-13-4-084
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A