Comparison of thromboelastometry with classical coagulation tests in cardiac surgery

Published: 16-07-2009
Last updated: 04-05-2024

Comparison of thromboelastometry and classical coagulation tests for perioperative evaluation of coagulation disturbances in patients undergoing cardiothoracic surgery

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON33435

Source
ToetsingOnline

Brief title
ROTEM study

Condition

- Cardiac therapeutic procedures

Synonym
Coagulation, hemostasis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bleeding, Cardio-thoracic surgery, Coagulation, Thromboelastometry

Outcome measures

Primary outcome

Level of comparison of ROTEM INTEM clotting time and aPTT (classical coagulation test)

Secondary outcome

Level of comparison of FIBTEM and Clauss test for fibrinogen.

Demographic variables: Age, gender, length, body weight, preoperative and postoperative hematocrit, hemoglobin, leukocyte count.

Surgical characteristics: Surgery time, clamp time, CPB time.

Medicine use: use of drugs that influence coagulation

Administration of blood products and fluid, urine production

Comparison of treatment decision based on classical coagulation parameters and ROTEM analysis.

Study description

Background summary

Patients undergoing cardiothoracic surgery are at risk for coagulation disorders due to perioperative bleeding and hemodilution due to the use of cardiopulmonary bypass (CPB). Optimal coagulation management during surgery is therefore of major importance in order to reduce the risk for postoperative bleeding complications. Recently, the VU University Medical Center (VUMC) introduced a thromboelastometry device (ROTEM, Pentapharm, Germany) in the operating rooms and intensive care unit in order to perform point-of-care evaluation of perioperative coagulation disturbances. The first step in implementation of this technique is to locally validate the device by comparison of ROTEM analyses with classical coagulation test like the activated

partial thromboplastin time (aPTT), prothrombin time (PT) and Clauss test for evaluation of fibrinogen as used in the VUMC. The present observational study therefore aims to systematically compare ROTEM analyses with classical coagulation tests in order to define the value of thromboelastometry in the perioperative and postoperative setting.

Study objective

Comparison of thromboelastometry and classical coagulation tests for perioperative evaluation of coagulation disturbances in patients undergoing cardiothoracic surgery

Study design

Observational, single center clinical trial

Study burden and risks

A peripheral intra-arterial catheter placement is standard perioperative procedure in all patients undergoing cardiothoracic surgery, and will therefore not add up to patient discomfort in the present study. Patients with anemia will be excluded from the present study (Hb < 5 mmol/l).

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV
Nederland
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing elective cardiothoracic surgery
Age 18-90 years
Preoperative hemoglobin of > 5.5 mmol/l
Informed consent

Exclusion criteria

Re-operations and emergency operations
Use of erythropoietin
Patients receiving blood transfusions < 1 month before surgery
Hepatic or renal failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009

Enrollment:	23
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL27966.029.09