Target Activated Clotting time for anticoagulation during cardiopulmonary bypass

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27592

Source
NTR

Brief title
TACT study

Health condition

Heart diseases

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Not decided

Intervention

Outcome measures

Primary outcome

Packed red blood cell (PRBC) transfusion rates during hospitalization

Secondary outcome

• 12 and 24-hour blood loss assessed by wound drainage
• Postoperative hemoglobin values at 1, 12 and 24 hours following surgery
• Reoperations due to bleeding
• Late tamponade
• Transfusion requirements (FFP, platelets, fibrinogen, PCC)
• Postoperative hemostatic parameters
• Use of preoperative anticoagulant medication
• Number of patients who do not reach the target ACT after the first heparin dose
• Total heparin and protamine dosing
• Postoperative restenosis of grafts
• Clotting of the extracorporeal circuit
• Thromboembolic events during and following surgery
• Mortality at 30 days, 90 days and 1 year following surgery
• Patient demographics

Study description

Background summary

Patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) require full anticoagulation to inhibit thrombin production, reduce clot formation and activation of the coagulation system. Worldwide, but also in the Netherlands, various target activated clotting time (ACT) values are used during CPB. While part of the centers use a target ACT > 480 seconds, others use an ACT > 400 seconds. Due to the lack of large randomized controlled trials in modern cardiosurgical settings it is unclear which target ACT is associated with the most favorable hemostatic profile following cardiac surgery. The present study therefore aims to investigate the impact of a minimal target ACT of 400 or 480 seconds, respectively, on transfusion rates, postoperative blood loss and reoperations in patients undergoing cardiac surgery with cardiopulmonary bypass.

Study objective

It is hypothesized that anticoagulation with a target ACT > 400 seconds is equivalent to a target ACT > 480 seconds with respect to packed red blood cell (PRBC) transfusion rates during hospitalization in patients undergoing cardiac surgery with cardiopulmonary bypass.

Study design

N/A

Intervention

Heparin anticoagulation during cardiopulmonary bypass with a target ACT of 400 seconds versus a target ACT of 480 seconds

Contacts

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Eligibility criteria

Inclusion criteria

• Patients scheduled for elective CABG or cardiac valve surgery, or a combination of CABG with valve surgery, or (cross-clamped) aortic root or ascendens procedures with cardiopulmonary bypass.
• Adult surgery
• Informed consent

Exclusion criteria

• Re-operations
• Aorta surgery (requiring SCP and/or circulatory arrest)
• Emergency operation
• Minimized extracorporeal circuits (MECC)
• Deep hypothermia (<32oC)
• Patients with congenital coagulation factor abnormalities (e.g. von Willebrand disease, hemophilia)
• Patients with acquired coagulation factor abnormalities (e.g. acquired haemophilia, acquired von Willebrand disease, haematological malignities, thrombocytopenia <75*109/L)
• Patients with anemia (hemoglobin value < 6.5 mmol/l)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	1536
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52711
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7575
CCMO	NL64741.041.18
OMON	NL-OMON52711

Study results