Target Activated Clotting Time for anticoagulation during cardiopulmonary bypass

Published: 20-02-2019
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Is targeting an ACT > 400 seconds equivalent compared to an ACT > 480 seconds with respect to PRBC transfusion rates during hospitalization in patients undergoing cardiac surgery with cardiopulmonary bypass?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON52711

Source
ToetsingOnline

Brief title
TACT study

Condition

- Coronary artery disorders

Synonym
bloodtransfusion, packed red blood cel transfusion

Research involving
Human

Sponsors and support

Primary sponsor: Perfusie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: activated clotting time, anticoagulation, blood transfusion, cardiopulmonary bypass

Outcome measures

Primary outcome

Overall packed red blood cell transfusion rate 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 (e.g. venous thrombosis, pulmonary embolism)

• 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) receive anticoagulation to inhibit thrombin production, reduce clot formation and activation of the coagulation system. The amount of anitocoagulant (heparin) necesary to reach the set target depends on both patient- and procedural characteristics. 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.

Study objective

Is targeting an ACT > 400 seconds equivalent compared to an ACT > 480 seconds with respect to PRBC transfusion rates during hospitalization in patients undergoing cardiac surgery with cardiopulmonary bypass?

Study design

Multicenter, single-blinded randomized controlled trial.

Intervention

1010 patients undergoing cardiac surgery with cardiopulmonary bypass are randomized into a group with target ACT >400 seconds or into a group with a target ACT >480 seconds.

Study burden and risks

Both the use of target ACT values of 400 and 480 seconds for extracorporeal circulation during cardiosurgical procedures are commonly used in hospitals in The Netherlands. Participation in this study does not add up to the patiënt risk. The risks of bleeding and thromboembolic events are currently estimated as comparable for both study arms, and estimate 2-5% of the patient population in accordance to routine cardiosurgical practice. Patients who do not participate in the TACT study will be subjected to an ACT according to the routine of the local hospital.

Contacts

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Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients undergoing elective cardiac surgery with cardiopulmonary bypass including coronary artery bypass grafting, valve surgery or a combination of both.
Informed consent.

Exclusion criteria

re-operations
aorta surgery
emergency operation
minimized extracorporeal circuits

deep hypothermia (<32 degrees Celsius)
patients with congenital or aquired coagulation factor abnormatlities
patients with anemia (hemoglobin values < 6.5 mmol/l)

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-11-2019
Enrollment:	1010
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-08-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	03-06-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-12-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-05-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27592
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64741.041.18
OMON	NL-OMON27592