The predictive value of platelet reactivity for post-operative blood loss and the use of blood transfusion products in patients after cardiac surgery

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1. Determine whether thrombo-elastography (TEG) the occurrence of postoperative blood loss and transfusions can predict after cardiac surgery.2. Determine whether platelet aggregometry (Multiplate and Verify Now) can predict the occurrence of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Platelet disorders
Study type	Observational invasive

Summary

ID

NL-OMON41725

Source
ToetsingOnline

Brief title
POPular Prophecy study

Condition

- Platelet disorders

Synonym
reduced platelet function, trombocytopathy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

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

Intervention

Keyword: cardiovascular surgery, platelet reactivity

Outcome measures

Primary outcome

The primary endpoint is defined as the total amount of blood loss during the first six hours after the operation

Secondary outcome

Secondary end-points are the total amount of blood loss during the first 12 and 24 hours after the operation, the number of transfused allogeneic blood products during the first 24 hours post-surgery, post-operative bleeding complications during hospitalization and re-operation due to a bleeding complication during the post-operative hospital stay.

Study description

Background summary

Cardiothoracic surgery is associated with blood loss and an increased risk of impaired coagulation by the use of a cardiopulmonary bypass (CPB). Coagulation is a process of primary hemostasis platelet adhesion and aggregation, followed by secondary
plasmatic coagulation and fibrin formation. Use of the CPB induces thrombocytopathy.
For the prevention of thromboembolic events CABG patients are preoperatively regularly treated with platelet aggregation inhibitors (APT = anti-platelet therapy). APT is in accordance with international guidelines perioperatively continued with an increased risk of bleeding complications, especially in continuing the P2Y12 inhibitors. The effect of APT is irreversible.
Point of Care clotting assay with platelet function tests give qualitative information on platelet aggregation and can contribute positively to earlky

goal directed blood transfusion after cardiac surgery.

Study objective

1. Determine whether thrombo-elastography (TEG) the occurrence of postoperative blood loss and transfusions can predict after cardiac surgery.
2. Determine whether platelet aggregometry (Multiplate and Verify Now) can predict the occurrence of postoperative blood loss and transfusions after cardiac surgery.
3. Definition of reference range for platelet aggregometry (Multiplate and Verify Now Aspirin assay) in patients during cardiac surgery.
4. Determine the value of TEG, Multiplate and Verify Now comparing with standard laboratory coagulation tests.

Study design

Single center, blinded observational study

Study burden and risks

This study is observational and does not affect the treatment. There is informed consent required for participation.
Elective cardiac surgery is done under general anesthesia. The anesthetic policy for a patient participating in the study, does not differ from a patient who is not taking part in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• > 18 years
• mentally competent
• scheduled for CABG + (multiple) heart valve surgery or multiple valve surgery
• signed informed consent

Exclusion criteria

• congenital or acquired clotting disorder
• pregnancy

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):	01-04-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 21551
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51434.100.14
Other	NTR nummer volgt
OMON	NL-OMON21551