Platelet function in minimal extracorporeal circulation versus conventional extracorporeal circulation in coronary artery bypass grafting

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This study evaluates if there is a difference in platelet function during and following the use of minimal ECC compared with conventional ECC in coronary artery bypass grafting (CABG) analysed with tromboelastography en multiple electrode aggrometry…

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

Summary

ID

NL-OMON37082

Source
ToetsingOnline

Brief title
Platelet function in minimal extracorporeal circulation in CABG

Condition

- Platelet disorders
- Coronary artery disorders
- Vascular therapeutic procedures

Synonym
platelet dysfunction, thrombocytopathy

Research involving
Human

Sponsors and support

Primary sponsor: anaesthesiologie
Source(s) of monetary or material Support: Standaard behandeling;geen extra kosten

Intervention

Keyword: minimal extracorporeal circulation, multiple electrode aggregometry, platelet function, tromboelastography

Outcome measures

Primary outcome

Results tromboelastography and multiple electrode aggregometry

Secondary outcome

perioperative blood loss

blood loss every hour after PACU/IC admission for 4 hours

total blood loss 24 hours after CABG

total amount of transfused packed cells perioperative

total amount of transfused packed cells 24 hours after CABG

total amount of transfused platelets perioperative

total amount of transfused platelets 24 hours after CABG

total amount of transfused fresh frozen plasma perioperative

total amount of transfused fresh frozen plasma 24 hours after CABG

Study description

Background summary

The introduction of cardiopulmonary bypass (CPB) in the 1950s has allowed development in heart surgery. Cardiopulmonary bypass is a safe and method with low mortality rates. Nevertheless morbidity in cardiopulmonary bypass is significant. Cardiopulmonary bypass leads to hemodilution, complement and white

cell activation with systemic inflammatory response, platelet activation, the need for intensive anticoagulation, systemic organ dysfunction and the frequent need for blood and blood products to control postbypass bleeding or blood loss. The pathofysiology is not fully elucidated but has been related to blood contact with foreign surface. Minimal-ECC circuits minimise foreign surface-blood interaction and are heparinized from tip to tip. The tubing legth has been shortened to decrease crystalloid prime. Cardiotomy suction is minimised. An active air-removal device is added to the closed circuit. The use of minimal ECC has already shown a significant reduction of the systemic inflammatory reaction and less perioperative transfusion of blood products.

Study objective

This study evaluates if there is a difference in platelet function during and following the use of minimal ECC compared with conventional ECC in coronary artery bypass grafting (CABG) analysed with tromboelastography en multiple electrode aggrometry.

Study design

Monocenter, prospective, observational, pilot study

Study burden and risks

None, an extra 46 ml of blood will be taken via an already inserted arterial line according to the standard protocol for coronary artery bypass surgery

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

- patients undergoing non emergency coronary artery bypass grafting using conventional extracorporeal circulation or minimal extracorporeal circulation
- 18 years and older
- left ventricle function >50%

Exclusion criteria

- emergency setting
- platelet function disorders before surgery
- thrombocytopenia
- renal insufficiency
- use of clopidogrel shorter than 5 days before surgery
- chronic alcohol abuse

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-10-2012
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

No registrations found.

In other registers

Register	ID
CCMO	NL40546.060.12