Thrombocyte function and the relationship to blood loss and need for transfusion during coronary artery bypass surgery.

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

Summary

ID

NL-OMON34435

Source
ToetsingOnline

Brief title
Thrombocyte function and transfusion during coronary bypass chirurgie.

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
Thrombocyte dysfunction during cardiac surgery

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Nodia, IPO Medical en mogelijk Siemens (Betreffende kit-korting),Onderzoeksbudget laboratorium;gedeeltelijk sponsoring van testleveranciers.

Intervention

Keyword: blood transfusion, coronary artery bypass surgery, thrombocyte function, thrombocyte transfusion

Outcome measures

Primary outcome

Outcome if the different labortory tests of platelet function

Blood loos during and within 24 hours after the surgical procedrue

Transfused number of units during and within 24 hours after the surgical

procedure

Secondary outcome

Correlation between the different thrombocyte function tests in the two studied

populations

Study description

Background summary

Cardiothoracal surgical procedures as coronary artery bypass grafting (CABG) are frequently accompanied by transfusions. Several studies have shown that extensive transfusion during and after the procedure is associated with a reduced prognosis of the patient. Risk factors that attribute to this are transfusion reactions, infections and immune suppression.

Several procedural issues (use of extracorporal circulation, hypothermia, haemodilution etc) reduce the thrombocyte function during the operation. Moreover, use of aspirin and clopidogrel result in an acquired thrombocytopathy, additionally reducing the functionality of the thrombocytes.

To prevent bleeding events thrombocyte concentrates are frequently transfused, predominantly in patients using clopidogrel. The transfusion is based on estimated and expected blood loss and not on laboratory testing of thrombocyte function. As the response of thrombocyte function on clopidogrel is highly variable, it is expected that many patiënt are transfused without adequate indication.

Nowadays several laboratory techniques are available that can be employed to estimate the thrombocyte function during the CABG-procedure. Established techniques are Light Transmission Aggregometry (LTA), thromboelastografy (TEG) and Multiple Electrode Aggregrometrie (MEA). Also, a new application has recently been launched for the Platelet Function Analyzer (PFA100) to specifically determine the effect of clopidogrel on platelet function. These techniques can potentially be used to measure thrombocyte function during the CABG-procedure and to base an effective thrombocyte transfusion decisions on, for an optimal patient care.

Study objective

The analysis is performed of thrombocyte function before, during and and after CABG surgery with dedicated tests as Light Transmission Aggregometry(LTA), thromboelastography (TEG), Multiple Electrode Aggregrometry (MEA) en Platelet Function Analyzer (PFA100) . De predictive value is determined of the separate testing procedures for peri- en post-operative blood loss and the number of transfused blood products. Calculations are performed in a patient group that has been treated with clopidogrel until the day of the procedure (in combination with aspirin) and in a patient group that has not been treated with clopidogrel for at least 5 days before the procedure and has only been treated with aspirin.

Study design

Monocenter, prospective, observational investigation

Study burden and risks

The burden during the study exists of blood sampling from mostly an arterial line on tree time points:
1. Before start of the surgical procedure.
2. Meteen Immediately after the surgical procedure after antagonisation of heparin
3. Later after the surgical procedure after arrival at the ICU

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
5602 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
5602 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Elective CABG-procedure with use of extracorporale circulation
Group 1: Minimum of 5 days use of clopidogrel and aspirin until day of procedure.
Group 2: Minimum of 5 days use of aspirin until the day of procedure, but no clopidogrel use for at least 5 days prior to the procedure.

Exclusion criteria

Use of coumarines or (low molecular weight) heparin
Clinical or laboratory signs of hemorrhagic diathesis
Cardiac failure
Renal insufficiency or dialysis

Liver failure
Chronic alcoholism
Age <18 years

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):	19-10-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	18-08-2010
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	NL32534.060.10