The CPB; fibrinoLysis Or Thrombosis? (CLOT) study, understanding the effects of CPB on coagulation and fibrinolysis to improve treatment of blood loss after cardiac surgery.

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The aim of the study is to understand the effects of CPB on coagulation and fibrinolysis to improve treatment of excessive blood loss (>2L/24 hours or >200 mL/hour) after cardiac surgery.The objective of this study is to differentiate between...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational non invasive

Summary

ID

NL-OMON35050

Source
ToetsingOnline

Brief title
CLOT study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Coronary artery disorders

Synonym
coagulation disturbance, Coagulopathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood loss, Cardiopulmonary bypass, Coagulation, Fibrinolysis

Outcome measures

Primary outcome

Several parameters will be studied in the collected blood samples, e.g.:

Coagulation:

- Aggregometer --> platelet aggregation

- Prothrombin time, Activated partial thromboplastin time, fibrinogen, D-dimer

- Platelets

Fibrinolysis:

Fibrinolytic assays (t-PA activity, PAI-I activity etc.)

Thromboelastography, Fluorescence Activated Cell Sorter

Secondary outcome

Peroperative:

- Operation time

- CPB time

- Aortic clamping time

Postoperative:

- Bloedtransfusions within 48 hours after surgery

- Amount of blood loss within 48 hours after surgery

- Total amount of blood loss after surgery

Study description

Background summary

Background
Excessive postoperative blood loss (>2L/24 hours or >200 mL/hour) is one of the most common complications of cardiac surgery, and a risk factor for prolonged mechanical ventilation, pneumonia, wound infection, sepsis, and mortality. A surgical cause of bleeding is only found in half of patients undergoing reoperation/re-exploration for bleeding. In the remainder of patients the cause is multifactorial and probably an acquired/surgical related hemostatic defect is responsible for diffuse, excessive blood loss.
Cardiac surgery with concomitant CPB can profoundly alter the hemostatic balance. Excessive activation of the hemostatic system, which is related to high doses of heparin, interaction of blood with the extensive, non-endothelial CPB surfaces, activation of the extrinsic clotting pathway secondary to surgical trauma and transfusion of pericardial blood with a thrombin-mediated factor consumptive process as result, primary fibrinolysis, and hemodilution contribute to dysfunction of the coagulation, fibrinolytic, and inflammatory systems that lead to a postoperative coagulopathy and, in some cases, excessive bleeding.
With the *CPB; fibrinoLysis Or Thrombosis* CLOT study, a study to investigate the effects of CPB on coagulation and fibrinolysis, we would like to broden our knowledge of the hemostatic blance before, during, and after cardiac surgery. The relative contributions of a factor consumptive process and fibrinolysis during operation, caused by the CPB and related proceedings, on the hemostatic balans of a patient during and after cardiac surgery will be studied. With the obtained data we would like to differentiate between a pro-thrombotic, a (post) factor consumptive process, and a (post)fibrinolytic state after cardiac surgery to improve the treatment of excessive blood loss at the ICU and to enlarge its cost-effectiveness.

Hypothesis
This study will test the hypothesis that the hemostatic balance of a patient after cardiac surgery is rather (post)DIC or (post)fibrinolytic, than pro-thrombotic.

Further we hypothese that longer use of CPB is associated with predomination of fibrinolysis to a disseminated intravascular coagulation (DIC) process.

Study objective

The aim of the study is to understand the effects of CPB on coagulation and fibrinolysis to improve treatment of excessive blood loss (>2L/24 hours or >200 mL/hour) after cardiac surgery.
The objective of this study is to differentiate between a pro-thrombotic, a (post)DIC, and a (post)fibrinolytic state after cardiac surgery. This differentiation might lead to an improvement of patient care and extend the cost effectiveness in the care of patients after cardiac surgery.

Study design

This is a multi center observational study in the LUMC in Leiden and Haga Hospital in The Hague, the Netherlands.

Study burden and risks

The measurements necessary to asses the defined study endpoints are not expected to negatively influence the result of treatment or patient condition.

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

* Coronary artery bypass graft (CABG), isolated and combined with aortic valve replacement (AVR)
* Left ventricle ejection fraction > 35%
* Age >18 years

Exclusion criteria

* Any other procedure than CABG whether or not combined with AVR
* Emergency surgery
* History of bleeding diathesis or coagulopathy
* Participation in any study involving an investigational drug or device
* Inability to understand the study information and/or sign informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	06-07-2010
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL31951.058.10