Different strategies of heparin management during cardiopulmonary bypass: the effects on anticoagulation and postoperative hemostasis

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The present study will investigate whether implementation of the Hemostasis Management System (HMS) in cardiothoracic surgery will result in higher doses of heparin and lower doses of protamine, thereby leading to a less impaired postoperative...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON34395

Source
ToetsingOnline

Brief title
HepCon study

Condition

- Cardiac therapeutic procedures

Synonym
Valve disease, valvular obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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

Intervention

Keyword: Cardiac surgery, Coagulation, Extracorporeal circulation, Heparinization

Outcome measures

Primary outcome

* Reduction in postoperative protamine usage

Secondary outcome

* Improvement of postoperative hemostasis

* Hemostatic monitoring (ROTEM Clotting Time (CT), ROTEM Maximum Clot Firmness (MCF) and the shear elastic modulus G (all ROTEM parameters)

* Pre-CPB and post-CPB aPTT, PT and Clauss fibrinogen test

* Heparin concentration and HR-ACT (both HMS), ACT (Hemochron)

* C-reactive protein (CRP), platelet count, perioperative transfusion requirements, perioperative fluid balance

* Patient demographics

* Surgery time, CPB time, cross-clamp time

Study description

Background summary

To prevent thrombin formation from occurring during cardiopulmonary bypass (CPB), the anticoagulant heparin is administered to the patient. Heparin may however inhibit platelet activation and fibrin polymerization and thus, among other actions, contribute to intra- and postoperative blood loss. Moreover, heparin needs to be counteracted by protamine, which is associated with disturbances in hemostasis and allergic reactions. Currently, the Activated Clotting Time (ACT) is used to dose heparin and protamine. Several studies however suggested that ACT-based heparin management is associated with

protamine over dosage. The present study will therefore evaluate whether heparin management using a more advanced Hemostasis Management System (HMS) may result in a reduction in protamine administration, and thereby preserve patient coagulation as measured by rotational thromboelastometry (ROTEM). The present study will therefore investigate whether implementation of the Hemostasis Management System (HMS) in cardiothoracic surgery will result in higher doses of heparin and lower doses of protamine, thereby leading to improved hemostasis after CPB as compared to ACT-guided heparin management.

Study objective

The present study will investigate whether implementation of the Hemostasis Management System (HMS) in cardiothoracic surgery will result in higher doses of heparin and lower doses of protamine, thereby leading to a less impaired postoperative hemostasis as compared to ACT-guided heparin management.

Study design

* Single-center prospective, randomized study
* The study will be performed in the departments of Cardio-thoracic surgery and Anesthesiology of the VUmc.
* Patients undergoing valve replacement and/or valve repair surgery
* ROTEM will be used to determine pre- and postoperative hemostasis in each patient
* Patients will be randomly assigned into two study groups which are based on the heparin management system used during cardiopulmonary bypass:
A: HMS Measurement of heparin concentration during CPB
B: ACT Measurement of ACT during CPB

Study burden and risks

A peripheral intra-arterial catheter placement is standard perioperative procedure in all patients undergoing cardiothoracic surgery, and will therefore not add up to patient discomfort in the present study.
Higher doses of heparin and lower doses of protamine might lead to a less impaired postoperative hemostasis.

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 valve replacement and/or valve repair surgery
* Age 18-85 years
* Informed consent

Exclusion criteria

* Re-operations
* Emergency operation
* Patients with insulin-dependent diabetes mellitus
* Patients with a history of hematologic, hepatic or renal diseases
* Patients with Body Mass Index (BMI) over 30 kg/m2

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2010
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Heparin Management System (HepCon)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL32254.029.10