# 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

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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**

#### **Public**

Vrije Universiteit Medisch Centrum

De Boelelaan 1117 1081 HV

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NL

#### Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117 1081 HV NL

## **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