# Heparin Influence on Anticoagulation and Perioperative Hemostasis during Arterial Vascular Surgery

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To measure individual heparin requirements in 30 patients undergoing arterial vascular

surgery.

**Ethical review** Approved WMO **Status** Recruitment stopped

**Health condition type** Vascular therapeutic procedures

**Study type** Observational invasive

# **Summary**

#### ID

NL-OMON38796

#### Source

ToetsingOnline

#### **Brief title**

HepaVasc study

## **Condition**

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

#### **Synonym**

Vascular disease, vascular surgery

## 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:** Coagulation, Hemostasis, Heparin, Vascular surgery

## **Outcome measures**

## **Primary outcome**

Individual target heparin concentration.

## **Secondary outcome**

Perioperative hemostasis

**Blood loss** 

# **Study description**

## **Background summary**

Worldwide, the anticoagulant heparin is administered to prevent thromboembolic complications in patients undergoing arterial vascular surgery. There is however no consensus with regard to perioperative heparin dosing requirements in these patients, although the side effects of heparin can be severe. Preliminary results from a heparin management study in patients undergoing cardiac surgery with cardiopulmonary bypass show individual differences in the response to heparin dosing among patients. In contrast to cardiothoracic surgery, there is however no standard monitoring of the effect of heparin during vascular surgery.

In this observational study we therefore would like to investigate the heparin requirements of patients undergoing arterial vascular surgery using the Hemostasis Management System (HMS; HMS Plus). The effects of heparin on coagulation in these patients will further be evaluated using rotational thromboelastometry. In this way a scientific foundation can be established to develop protocolized heparin management in arterial vascular surgery.

## **Study objective**

To measure individual heparin requirements in 30 patients undergoing arterial vascular surgery.

## Study design

Observational patient cohort study.

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## Study burden and risks

Patients will be subjected to intraoperative blood sampling (5 times 8 ml). Blood sampling will be performed while patients are under anesthesia using an existing intravenous catheter, and this is therefore not associated with an additional burden for the patient.

# **Contacts**

#### **Public**

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De Boelelaan 1117 Amsterdam 1081 HV NL

#### **Scientific**

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# **Trial sites**

## **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

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

## Inclusion criteria

- \* Adult patients (18-85 years)
- \* Elective arterial vascular surgery

\* Informed consent

## **Exclusion criteria**

- \* Re-operation
- \* Emergency surgery

# 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): 15-01-2014

Enrollment: 30

Type: Actual

# **Ethics review**

Approved WMO

Date: 17-12-2013

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 NL45906.029.13