Heparin Influence on Anticoagulation and Perioperative Hemostasis during Arterial Vascular Surgery

Published: 17-12-2013
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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.

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

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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