Meten van de geactiveerde stollingstijd tijdens slagaderlijke vaatingrepen.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29650

Source
NTR

Brief title
MANCO

Health condition

ACT; Heparin; Arterial; Non-cardiac vascular surgery; Hemostasis Management System

Sponsors and support

Primary sponsor: dr. Arno M. Wiersema, Westfriesgasthuis.
Source(s) of monetary or material Support: Grant by Medtronic

Intervention

Outcome measures

Primary outcome

Percentage of patients reaching an ACT of 250 seconds by administering a standardized bolus of 5000 IU.

Total dose of heparin needed to reach 250 seconds.

Secondary outcome

evaluation of predictive value of HMS to reach ACT of 250 seconds by predicted dose of heparin.

All (anti)coagulation related events.

Study description

Background summary

Aim of the MANCO study is to establish for once and for all that monitoring the effect of heparin during Non-Cardiac Vascular interventions is essential to ensure the individual patient of safe and tailor-made anticoagulation. Not measuring the effect of the administered heparin exposes the patient to unnecessary risks of thrombo-embolic and bleeding complications. First aim of the MANCO study is to prove that the standardized bolus of 5000 IU of heparin, used by 90% of vascular specialists in Europe, results in inadequate anticoagulation in more than 80% of patients ACT less than 250 seconds). These measurements will be performed using the Hemostasis Management System by Medtronic. The calculated heparin dose using the HMS will be evaluated to test its predictive value to ensure every patient of tailor-made anticoagulation, thereby reducing the avoidable risks of thrombo-embolic and bleeding complications.

Study objective

Aim of the MANCO study is to establish for once and for all that monitoring the effect of heparin during NCVI is essential to ensure the individual patient of safe and tailor-made anticoagulation. Not measuring the effect of the administered heparin exposes the patient to unnecessary risks of thrombo-embolic and bleeding complications. First aim of the MANCO study is to prove that the standardized bolus of 5000 IU of heparin, used by 90% of vascular specialists in Europe, results in inadequate anticoagulation in more than 80% of patients. These measurements will be performed using the Hemostasis Management System by Medtronic„µ. The calculated heparin dose using the HMS will ensure every patient of tailor-made anticoagulation, thereby reducing the avoidable risks of thrombo-embolic and bleeding complications.

Study design

30 days after intervention or same admission; 6 weeks; 6 months; 12 months

Intervention

To evaluate if the current practice of using a standardized bolus of 5000 IU of heparin during

NCVI causes adequate periprocedural anticoagulation in the individual patient. This evaluation will be performed using the HMS. The calculated heparin dose response curve will be evaluated on the desired value of the ACT of 250 seconds. All participating centers and vascular surgeons and/or IR are allowed to apply their local heparin protocols.

Contacts

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Eligibility criteria

Inclusion criteria

All patients undergoing open or endovascular arterial non-cardiac arterial surgery aged more than 18 years.

Exclusion criteria

All patients undergoing open or endovascular arterial non-cardiac arterial surgery aged younger than 18 years. Dialysis dependend or EGFR < 30 ml/min.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2016
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-01-2018
Application type:	First submission

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
NTR-new	NL6788
NTR-old	NTR6973

Register	ID
Other	METC Noord-Holland : MO16-045

Study results