Meten van de geactiveerde stollingstijd tijdens slagaderlijke vaatingrepen.

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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29650

Bron
NTR

Verkorte titel
MANCO

Aandoening

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

Ondersteuning

Primaire sponsor: dr. Arno M. Wiersema, Westfriesgasthuis.
Overige ondersteuning: Grant by Medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2016
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6788
NTR-old	NTR6973

Register	ID
Ander register	METC Noord-Holland : MO16-045

Resultaten