

Thromboelastometry-based Assessment of Coagulation In Aortic Dissection

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The aim of the present retrospective and prospective data collection is to estimate the incidence and degree of perioperative coagulation abnormalities, using thromboelastometry (with both ROTEM® Delta and ROTEM® Sigma), as well as transfusion and...

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

Samenvatting

ID

NL-OMON26674

Bron

NTR

Verkorte titel

TACIT

Aandoening

Aortic dissection, both elective and emergency aortic surgery

Ondersteuning

Primaire sponsor: Department of Anesthesia, Amsterdam UMC, location AMC

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Comparison of standard-of-care thromboelastometry with ROTEM® Delta and ROTEM® Sigma at different timepoints perioperatively, in patients undergoing elective and emergency

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of the present retrospective and prospective data collection is to estimate the incidence and degree of perioperative coagulation abnormalities using thromboelastometry (with both ROTEM® Delta and ROTEM® Sigma) as well as transfusion and coagulation factor requirements in patients undergoing aortic surgery (emergency and elective). We will collect data on patients scheduled for emergency surgery, due to acute type A aortic dissection and patients undergoing elective surgery of the aorta. Furthermore, we will compare the results from viscoelastic testing using ROTEM® Delta with ROTEM® Sigma.

The findings may help to optimize coagulation management in patients undergoing major aortic surgery, in order to minimize bleeding as well as thromboembolic complications, both of which can have devastating consequences in this high-risk patient population.

Doel van het onderzoek

The aim of the present retrospective and prospective data collection is to estimate the incidence and degree of perioperative coagulation abnormalities, using thromboelastometry (with both ROTEM® Delta and ROTEM® Sigma), as well as transfusion and coagulation factor requirements, in patients undergoing elective and emergency aortic surgery.

Onderzoeksopzet

All available perioperative timepoints: T0 = Baseline (before aortic cross-clamp), T1 = after aortic cross-clamp, T2 = admission to ICU, T3 = post-op day 1 ICU, T4,5= (optional) daily on ICU until discharge from ICU, T6 = 30 day follow-up for morbidity and mortality

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Amsterdam Universiteits Medisch Centrum. locatie AMC
Jennifer Breel

0610019257

Wetenschappelijk

Amsterdam Universiteits Medisch Centrum. locatie AMC
Jennifer Breeel

0610019257

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients > 18 years
- Patients already operated on or scheduled for acute or elective aortic surgery in Amsterdam UMC, location AMC in period 01 January 2021 - 31 December 2021
- Willing and able to sign consent letter for the re-use of care data

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous history of manifest coagulation disorders

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-06-2021
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	06-06-2021
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	NL9530
Ander register	METC AMC : W21_186#21.201

Resultaten