Target Activated Clotting time for anticoagulation during cardiopulmonary bypass

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It is hypothesized that anticoagulation with a target ACT > 400 seconds is equivalent to a target ACT > 480 seconds with respect to packed red blood cell (PRBC) transfusion rates during hospitalization in patients undergoing cardiac surgery…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27592

Bron
NTR

Verkorte titel
TACT study

Aandoening

Heart diseases

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Not decided

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Packed red blood cell (PRBC) transfusion rates during hospitalization

Toelichting onderzoek

Achtergrond van het onderzoek

Patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) require full anticoagulation to inhibit thrombin production, reduce clot formation and activation of the coagulation system. Worldwide, but also in the Netherlands, various target activated clotting time (ACT) values are used during CPB. While part of the centers use a target ACT > 480 seconds, others use an ACT > 400 seconds. Due to the lack of large randomized controlled trials in modern cardiosurgical settings it is unclear which target ACT is associated with the most favorable hemostatic profile following cardiac surgery. The present study therefore aims to investigate the impact of a minimal target ACT of 400 or 480 seconds, respectively, on transfusion rates, postoperative blood loss and reoperations in patients undergoing cardiac surgery with cardiopulmonary bypass.

Doel van het onderzoek

It is hypothesized that anticoagulation with a target ACT > 400 seconds is equivalent to a target ACT > 480 seconds with respect to packed red blood cell (PRBC) transfusion rates during hospitalization in patients undergoing cardiac surgery with cardiopulmonary bypass.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Heparin anticoagulation during cardiopulmonary bypass with a target ACT of 400 seconds versus a target ACT of 480 seconds

Contactpersonen

Publiek

University Medical Center Utrecht
Karin Gorter

0628290901

Wetenschappelijk

University Medical Center Utrecht
Karin Gorter

0628290901

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients scheduled for elective CABG or cardiac valve surgery, or a combination of CABG with valve surgery, or (cross-clamped) aortic root or ascendens procedures with cardiopulmonary bypass.
• Adult surgery
• Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Re-operations
• Aorta surgery (requiring SCP and/or circulatory arrest)
• Emergency operation
• Minimized extracorporeal circuits (MECC)
• Deep hypothermia (<32oC)
• Patients with congenital coagulation factor abnormalities (e.g. von Willebrand disease, hemophilia)
• Patients with acquired coagulation factor abnormalities (e.g. acquired haemophilia, acquired von Willebrand disease, haematological malignities, thrombocytopenia <75*109/L)
• Patients with anemia (hemoglobin value < 6.5 mmol/l)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	1536
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:	05-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52711
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7575
CCMO	NL64741.041.18

Register	ID
OMON	NL-OMON52711

Resultaten