De effecten van verschillende doseringsverhoudingen van middelen die de stolling remmen of activeren op bloedverlies tijdens hartchirurgie.

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It is hypothesized that a low protamine-to-heparin ratio leads to improved hemostasis after cardiac surgery with cardiopulmonary bypass as compared to a high ratio as measured by rotational thromboelastometry, and reduces postoperative blood loss...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22454

Bron
NTR

Verkorte titel
Ratio-PRO study

Aandoening

Cardiac surgery; coronary artery bypass graft surgery; cardiopulmonary bypass

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Department of Cardio-thoracic surgery, VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative 24-hour blood loss assessed by wound drainage.

Toelichting onderzoek

Achtergrond van het onderzoek

Prior to, and during cardiopulmonary bypass, heparin is transfused in order to avoid massive coagulation activation by the contact surface of the heart-lung-machine. Heparin dosing is commonly based on bodyweight and activated clotting time (ACT). After cardiopulmonary bypass, protamine is transfused to neutralize heparin, thereby reactivating the clotting cascade. Protamine forms a 1:1 salt complex with heparin, but may exhibit an intrinsic anticoagulant activity after overdosing.
According to current guidelines, protamine dosing is performed in a 1.0-1.3:1.0 ratio with heparin. However, our own observations and several literature reports suggest that, due to the degrading and loss of heparin during surgery, protamine is usually overdosed. The consequent overdosing of protamine might deteriorate postoperative hemostasis. The present study investigates whether the use of a lower dosing protamine-to-heparin dosing ratio (0.8) is superior as compared to a high protamine-to-heparin dosing ratio (1.3) with respect to postoperative hemostasis, blood loss and transfusion.

Doel van het onderzoek

It is hypothesized that a low protamine-to-heparin ratio leads to improved hemostasis after cardiac surgery with cardiopulmonary bypass as compared to a high ratio as measured by rotational thromboelastometry, and reduces postoperative blood loss and blood product transfusion.

Onderzoeksopzet

At three time points during cardiac surgery (before cardiopulmonary bypass, and at 3 and 30 minutes following protamine administration, blood samples are drawn for further analysis. Postoperative hemostasis monitoring continues until 24 hours following surgery.

Onderzoeksproduct en/of interventie

Prior to and during cardiopulmonary bypass heparin is transfused in order to avoid massive coagulation activation by the contact surface of the heart-lung-machine. This administration is based on the bodyweight and activated clotting time (ACT) of the patient after heparin administration. Protamine is transfused after cardiopulmonary bypass in order to inactivate

the heparin and thereby reactivate clotting. It does so by forming a 1:1 salt complex with heparin. The protamine dosing is according to current guidelines done in a 1.0-1.3 : 1.0 ratio with heparin. However it is suggested that due to the degrading and loss of heparin during surgery using this approach protamine is overdosed when transfused. Since protamine itself has anticoagulant properties this would deteriorate postoperative hemostasis.

Therefore this study investigates if the use off a lower dosing ratio (0.8) is superior as compared to the general protamine dosing, a high protamine-to-heparin dosing ratio (1.3).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients undergoing coronary artery bypass graft (CABG) surgery;

2. Age 18-85 years;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Re-operations;

2. Emergency operation;

3. Patients with a history of hematologic disorders or renal replacement therapy;

4. Patients with a body mass index (BMI) below 18 kg/m2 or above 35 kg/m2.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	98
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3380
NTR-old	NTR3528
Ander register	VU / ABR : CCH2012-02 / NL40764.029.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A