Perioperatieve veranderingen in de microvasculaire perfusie in patiënten die coronaire bypass chirurgie ondergaan.

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The primary endpoint of this study is the change in perfused boundary region (PBR) during cardiopulmonary bypass (CPB). We assume that a heparin coated extracorporeal circuit, due to its comparable biochemical structure, is more biocompatible with...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25389

Bron
Nationaal Trial Register

Verkorte titel
GlyCar study

Aandoening

Cardiac surgery, Coronary Artery Bypass Grafting (CABG), Cardiopulmonary Bypass (CPB), microcirculation

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Perioperative changes in the perfused boundary region of the sublingual microvasculature.

Toelichting onderzoek

Achtergrond van het onderzoek

The endothelial glycocalyx (EGC) is a gel-like layer that acts as a natural coating for endothelial cells, thereby preventing these cells from having direct contact with circulating blood cells. In order to reduce the inflammatory and procoagulant response during cardiopulmonary bypass in patients undergoing cardiac surgery through contact activation, extracorporeal circuits are coated with a biocompatible surface. In VU University Medical Center, cardiopulmonary bypass is mostly performed using a heparin-coated extracorporeal circuit in combination with full anticoagulation by heparin administration. A heparin coated extracorporeal circuit might be more biocompatible with the endothelial glycocalyx, due to its comparable biochemical structure. Alternatively, a phosphorylcholine-coated extracorporeal circuit is used. The present study investigates whether the use of the heparin-coated extracorporeal circuit will contribute to the preservation of the glycocalyx during cardiac surgery, when compared to the phosphorylcholine-coated circuit.

Doel van het onderzoek

The primary endpoint of this study is the change in perfused boundary region (PBR) during cardiopulmonary bypass (CPB). We assume that a heparin coated extracorporeal circuit, due to its comparable biochemical structure, is more biocompatible with the endothelial glycocalyx. Hence, the increase of PBR will be more pronounced with the use of a phosphorylcholine-coated extracorporeal circuit. Therefore, it is hypothesized that the use of the heparin-coated extracorporeal circuit is associated with less severe disturbances of the perfused boundary region than the phosphorylcholine-coated circuit.

Onderzoeksopzet

Blood will be drawn and several microcirculatory imaging parameters will be measured before surgery (T0), before (T1) and after administration of heparin (T2), after initiation of CPB (T3), after placement of the side clamp (T4), after administration of protamine (T5), after infusion of concentrated red blood cells (T6), 3 hours after the patient has arrived at the ICU (T7), and 24 hours (T8) and 72 hours (T9) following surgery.

Onderzoeksproduct en/of interventie

The endothelial glycocalyx (EGC) is a gel-like layer that acts as a natural coating for endothelial cells, thereby preventing these cells from having direct contact with circulating blood cells. In order to reduce the inflammatory and procoagulant response during cardiopulmonary bypass in patients undergoing cardiac surgery through contact activation, extracorporeal circuits are coated with a biocompatible surface. In VU University Medical

Center, cardiopulmonary bypass is mostly performed using a heparin-coated extracorporeal circuit in combination with full anticoagulation by heparin administration. Alternatively, a phosphorylcholine-coated extracorporeal circuit is used, but it is unknown how these different biocompatible-coated extracorporeal circuits will contribute to the preservation of the glycocalyx during cardiac surgery.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult patients undergoing CABG surgery (18-85 years);

2. Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Re-operations;

2. Emergency operation;

3. Patients with diabetes mellitus;

4. Patients with a history of hematologic disorders or hepatic disease or renal replacement therapy;

5. Patients with a body mass index (BMI) above 35 kg/m2.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2013
Aantal proefpersonen:	44
Type:	Verwachte 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	NL4045
NTR-old	NTR4212
Ander register	VU University Medical Center / ABR : CCH2013-291 / NL45828.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A