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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25389

Source
Nationaal Trial Register

Brief title
GlyCar study

Health condition

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

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: VU University Medical Center

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Shedding of Syndecan-1, heparan sulphate and hyaluronic acid.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Dept. of Cardio-thoracic surgery
VU University Medical Center
De Boelelaan 1117
A.B.A. Vonk
Amsterdam 1081 HV
The Netherlands
Scientific
Dept. of Cardio-thoracic surgery
VU University Medical Center
De Boelelaan 1117
A.B.A. Vonk
Amsterdam 1081 HV
The Netherlands

Eligibility criteria

Inclusion criteria

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

2. Informed consent

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	44
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4045
NTR-old	NTR4212
Other	VU University Medical Center / ABR : CCH2013-291 / NL45828.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A