Perioperative changes in the microvascular perfused boundry region in patients undergoing coronary artery bypass grafting

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21929

Source
Nationaal Trial Register

Brief title
GlyCar

Health condition

Microcirculation, Glycocalyx, Cardiac surgery, Heparin, Cardiovascular disease

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 boundry region (PBR) of the sublingual

microvasculature

Secondary outcome

Perioperative changes in plasma markers for shedding of the glycocalyx such as heparan sulfate, hyaluronic acid and syndecan-1

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 Centre, cardiopulmonary bypass is mostly performed using a heparin-coated extracorporeal circuit in combination with full anticoagulation by heparin infusion. 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.

Study objective

We assume that the increase of perfused boundry region will be more pronounced with the use of a phosphorylcholine-coated extracorporal circuit then with the use of a heparin-coated extracorporeal 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

none

Contacts

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Eligibility criteria

Inclusion criteria

adult patients (age 18-85 years) undergoing CABG surgery, informed consent

Exclusion criteria

Re-operation, emergency operation, patients with diabetes mellitus type 1, patients with a history of hematologic or hepatic diseases or renal replacement therapy, patients with a Body Mass Index (BMI) over 35 kg/m2

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	44
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-10-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38499
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4085
NTR-old	NTR4222
CCMO	NL45828.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38499

Study results

Summary results
N/A