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

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To identify the influence of two different biocompatible-coated extracorporeal circuits on the perfused boundary region of the sublingual microvasculature as measured by the GlycoCheck Sidestream Darkfield Imaging camera.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38499

Source
ToetsingOnline

Brief title
GlyCar study

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
Coronary ischemia, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac surgery, Glycocalyx, Heparin, Microcirculation

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 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

To identify the influence of two different biocompatible-coated extracorporeal circuits on the perfused boundary region of the sublingual microvasculature as measured by the GlycoCheck Sidestream Darkfield Imaging camera.

Study design

Single-center prospective, randomized study in the VU University Medical Center.

Study burden and risks

Both extracorporeal circuits are part of daily clinical care during cardiothoracic surgery and will not add up to patient risk and burden. Intravital microscopic imaging of the sublingual microvasculature by means of the GlycoCheck is a noninvasive measurement and will take before, during and up to 72 hours following surgery. A total of 80 ml of extra blood will be drawn from an existing intra-arterial line while the patient is under anesthesia. The intra-arterial line is part of routine clinical care in cardiac surgery, and will therefore not add up to patient discomfort in the present study.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients undergoing CABG surgery (age 18-85 years)
Informed consent

Exclusion criteria

* Re-operation
* Emergency operation
* Patients with diabetes mellitus type I
* Patients with a history of hematologic or hepatic disease or renal replacement therapy
* Patients with Body Mass Index (BMI) over 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
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2013
Enrollment:	44
Type:	Actual

Medical products/devices used

Generic name:	GlycoCheck & Extracorporeal system as part of routine

	clinical care
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21929
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45828.029.13
OMON	NL-OMON21929