Preservation of microcirculatory perfusion after pulsatile cardiopulmonary bypass: the role of prothrombogenic processes and the endothelium.

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We aim to investigate whether pulsatile flow in patients subjected to CPB preserves postoperative microcirculatory perfusion by prevention of a prothrombogenic profile and endothelial activation as are both present under non-pulsatile flow…

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

Summary

ID

NL-OMON36700

Source
ToetsingOnline

Brief title
PULSATILE II

Condition

- Coronary artery disorders

Synonym
bypass operation, cardiac surgery

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: Endothelial function, Microcirculatory perfusion, Pulsatile cardiopulmonary bypass

Outcome measures

Primary outcome

Change in microcirculatory perfusion, sublingual erythrocyte velocity,

capillary diameter and capillary density.

Secondary outcome

Change in fibrin network formation, platelet aggregation, endothelial function,

fybrinolysis and red blood cell deformability.

Study description

Background summary

Non-pulsatile cardiopulmonary bypass (CPB) during cardiac surgery is associated with postoperative disturbances in microcirculatory perfusion, which are prevented by reinstatement of pulsatile flow. Moreover, impaired microcirculatory perfusion after non-pulsatile flow correlates with the presence of prothrombogenic markers. The question arises whether prothrombogenic alterations are indeed related to disturbances in microcirculatory perfusion, and how this relation is affected by non-pulsatile and pulsatile CPB. Furthermore, it is unknown whether the relation of a prothrombogenic profile with microcirculatory perfusion involves distinct alterations in endothelial function.

Study objective

We aim to investigate whether pulsatile flow in patients subjected to CPB preserves postoperative microcirculatory perfusion by prevention of a prothrombogenic profile and endothelial activation as are both present under non-pulsatile flow conditions.

Study design

Single-center prospective, randomized study in the VUmc

Intervention

The intervention consists of the application of one type of cardiopulmonary bypass (conventional or pulsatile CPB). All interventions are part of standard clinical care.

Study burden and risks

Surgery: Both types of surgery are routinely used during cardiothoracic surgery and will not add up to patient risk and burden. SDF-imaging: Sublingual measurements of the microcirculation will be performed, meaning that the SDF-device has to be partially placed intra-oral. Since this is a non-invasive procedure, which is only performed during anesthesia, the burden for patients is considered minimal. Blood sampling: A total of 112 ml of extra blood will be sampled during CABG surgery and ICU admission from an existing intra-arterial line. Blood drawing is performed while the patient is under anesthesia, and will not add up to patient discomfort in the present study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing coronary artery bypass graft (CABG) surgery
Age 40-85 years
Informed consent

Exclusion criteria

Re-operations and emergency operations
Patients with insulin-dependent diabetes mellitus
Patients with a body mass index (BMI) > 35 kg/m²
Patients with anemia (Hb <5.5 mmol/l)

Study design

Design

Study type:	Observational 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):	28-06-2011
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Cardiopulmonary bypass using heart-lung machine
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-03-2011
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

No registrations found.

In other registers

Register	ID
CCMO	NL34947.029.10