Microcirculatory changes during cardiac surgery: The effects of different modalities of cardiopulmonary bypass

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Does CPB affect microcirculatory function by comparing on-pump (CON-CPB) and off-pump (OFF-PUMP) cardiothoracic surgery?Does pulsatile flow during cardiopulmonary bypass (PULSE-CPB) improve microcirculatory function as compared to continuous flow (...

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

Summary

ID

NL-OMON33586

Source
ToetsingOnline

Brief title
PULSATILE study

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
Coronary stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiopulmonary bypass, Cardiothoracic surgery, Microcirculation, Pulsatile flow

Outcome measures

Primary outcome

Change in microcirculatory perfusion, sublingual erythrocyte velocity, capillary diameter and capillary density.

Secondary outcome

Blood samples (in total 50 ml): creatinine, CK-MB, lactate, pH, HCO3-, nitrite/nitrate, prostacyclin, angiotensin II, IL-6, IL-10, TNF-alpha, free hemoglobin.

Urine output, fluid balance, hemodynamic variables, left ventricle function, venous saturation, need for intra-aortic balloon pump, need for inotropic medication, ventilation time.

Preoperative: demographic variables, left-ventricle function, serum creatinine, Euroscore (cardiac operative risk evaluation).
Intraoperative: number of anastomoses, bypass-time, cross-clamp time, pump flow during CPB, temperature during CPB, MAP during CPB, energy equivalent pressure during CPB.

Microcirculation measurement during ICU admission.

Study description

Background summary

Patients undergoing cardio-thoracic surgery are connected to a heart-lung machine and subsequently subjected to cardiopulmonary bypass (CBP) in order to bypass heart and lungs. Although CPB in major resembles body physiology, there are indications that the use of a heart-lung machine coincides with a reduced perfusion of the microvasculature. This may result in hypo-oxygenation of peripheral tissue and an impropriate removal of metabolites. There are indications that the use of pulsatile flow during CPB, which resembles circulation physiology, may improve microcirculatory perfusion during cardiac surgery. Here we aim to investigate the effect of pulsatile CPB (PULSE-CPB) on microcirculatory perfusion in comparison with conventional and mini-CPB (CON-CPB and MINI-CPB) and off-pump surgery (OFF-PUMP). Our investigation may contribute to optimalization of CPB techniques during cardio-thoracic surgery.

Study objective

Does CPB affect microcirculatory function by comparing on-pump (CON-CPB) and off-pump (OFF-PUMP) cardiothoracic surgery?

Does pulsatile flow during cardiopulmonary bypass (PULSE-CPB) improve microcirculatory function as compared to continuous flow (CON-CPB) or a mini-CPB (MINI-CPB) system?

Study design

Single-center prospective, randomized study in the VUmc

Study burden and risks

All described types of surgery (on-pump and off-pump) 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
Extra blood (50 ml) will be sampled during CABG surgery from the CPB blood container while the patient is under anesthesia. The first 25 ml will be drawn before onset of CPB, the second 25 ml just after removing the aortic cross

clamp. Since blood drawing is performed while the patient is under anesthesia, this 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 CABG surgery
Age 18-85 years
Informed consent

Exclusion criteria

Re-operations
Emergency operation
Patients with insulin-dependent diabetes mellitus
Patients with Body Mass Index (BMI) over 30 kg/m2

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2009
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	NL24707.029.08