Pulsatile II study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21204

Source
NTR

Brief title
Pulsatile II

Health condition

coronary artery bypass graft surgery, pulsatile cardiopulmonary bypass, microcirculatory perfusion, endothelial function, platelet aggregation, fibrinolysis

Sponsors and support

Primary sponsor: VU Medisch Centrum; Amsterdam
Source(s) of monetary or material Support: European Association for Cardiothoracic Anesthesiologists
Institute for Cardiovascular Research
Department of Anesthesiology

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Platelet aggregation;

2. Fibrin formation/degradation;

3. Red blood cell deformability;

4. Endothelial barrier function;

5. Endothelial biomarker expression.

Study description

Background summary

Rationale:

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.

Objectives:

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.

Study population:

Patients undergoing elective coronary bypass graft surgery (CABG; n = 48). Patients will be randomly assigned into two study groups:

1. Non-pulsatile flow: Continuous flow during CPB;

2. Pulsatile flow: Pulsatile flow during CPB.

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.

Main study parameters/endpoints:

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

Study objective

Pulsatile flow during cardiopulmonary bypass (CPB) results in preservation of microcirculatory function in the early postoperative period as compared to non-pulsatile CPB.

Study design

Measurements take place during the day of the operation and end within 4 hours after the operation.

Intervention

Pulsatile cardiopulmonary bypass vs. non-pulsatile cardiopulmonary bypass.

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Eligibility criteria

Inclusion criteria

1. Patients undergoing coronary artery bypass surgery (CABG);

2. Age 40-85 years;

3. Informed consent.

Exclusion criteria

1. Re-operations and emergency operations;

2. Patients with insulin-dependent diabetes mellitus;

3. Patients with a body mass index (BMI) > 35 kg/m2;

4. Patients with anemia (Hb < 5.5 mmol/l).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2011
Enrollment:	48
Type:	Actual

Ethics review

Positive opinion

Date:	16-06-2011
Application type:	First submission

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	NL2799
NTR-old	NTR2940
Other	VUMC Department of anesthesiology : ANES2010/070
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A