Pulsatile II study.

Gepubliceerd: 16-06-2011 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21204

Bron
NTR

Verkorte titel
Pulsatile II

Aandoening

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

Ondersteuning

Primaire sponsor: VU Medisch Centrum; Amsterdam
Overige ondersteuning: European Association for Cardiothoracic Anesthesiologists
Institute for Cardiovascular Research
Department of Anesthesiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Pulsatile cardiopulmonary bypass vs. non-pulsatile cardiopulmonary bypass.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Age 40-85 years;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-06-2011

Aantal proefpersonen:	48
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2799
NTR-old	NTR2940
Ander register	VUMC Department of anesthesiology : ANES2010/070
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A