Renal function after pulsatile blood flow during cardiopulmonary bypass in cardiac surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21086

Source
Nationaal Trial Register

Brief title
REPULS

Health condition

Cardiac surgery; Renal function; Cardiopulmonary bypass;

Sponsors and support

Primary sponsor: VU University Medical Center
UMCG
Source(s) of monetary or material Support: VU University Medical Center

Intervention

Outcome measures

Primary outcome

Relative change in serum creatinine levels in postoperative period

Secondary outcome

Postoperative urine production in ml;

Serum urea levels, creatinine clearance, glomerular filtration rate;

Nadir DO2, DO2/VCO2 ratio;

Sublingual microcirculatory perfused vessel density and perfused boundary region (n=40);

Microcirculatory and tissue oxygenation O2C levels (n=40);

Prevalence of renal replacement therapy

Study description

Study objective

Pulsatile blood flow during CPB reduces the relative increase in perioperative creatinine levels after cardiac surgery in patients with preoperative renal dysfunction

Study design

T0= blood + urine sample

T1= blood sample + buccal hemoglobin oxygenation

T2 = hemoglobin + microciculatory measurements

T3= hemoglobin + microciculatory measurements+ buccal hemoglobin oxygenation

T4 = blood + urine sample + microciculatory measurements+ buccal hemoglobin oxygenation

T5 = blood + urine sample + microciculatory measurements

T6 = blood + urine sample + microciculatory measurements+ buccal hemoglobin oxygenation

T7 = blood + urine sample.

Intervention

Patients will be randomly assigned to the following study groups:

- non-pulsatile bloodflow during CPB

- pulsatile bloodflow during CPB

Microcirculatory perfusion will be measured sublingually with an SDF camera. Buccal hemoglobin oxygenation will be measured with reflectance spectrophotometry. Extra blood will be drawn from an existing radial artery catheter. Urine samples will be gathered.

DO2/VO2/VCO2 values are measured with the heartlink monitor.

Contacts

Public
VU University Medical Center, Department of Anesthesiology
Christa Boer
De Boelelaan 1117
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4443830
Scientific
VU University Medical Center, Department of Anesthesiology
Christa Boer
De Boelelaan 1117
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4443830

Eligibility criteria

Inclusion criteria

Adult subjects with written informed consent (age 18-90 years) undergoing elective cardiac surgery with cardiopulmonary bypass; Patients with preoperative renal dysfunction (GFR <50 mL/min/1.73m2) or patients with diabetes mellitus and a GFR <60 mL/min/1.73m2 based on the CKD-EPI formula.

Exclusion criteria

- Emergency operations;

- Patients with previous heart surgery;

- Renal failure requiring preoperative renal replacement therapy (RRT)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2014
Enrollment:	294
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-10-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47075
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4680
NTR-old	NTR4832
CCMO	NL50135.029.14
OMON	NL-OMON47075

Study results