REnal function after PULSatile blood flow during cardiopulmonary bypass in cardiac surgery

Published: 16-10-2014
Last updated: 15-05-2024

Does pulsatile blood flow during cardiopulmonary bypass lead to a reduction in the average increase in postoperative creatinine levels in patients with preoperative renal dysfunction when compared to non-pulsatile blood flow?

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

Summary

ID

NL-OMON47075

Source
ToetsingOnline

Brief title
REPULS study

Condition

- Coronary artery disorders
- Renal disorders (excl nephropathies)
- Cardiac therapeutic procedures

Synonym
acute kidney injury, Renal dysfunction

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: Acute kidney injury, Blood flow, Cardiac surgery, Renal function

Outcome measures

Primary outcome

The relative change in serum creatinine levels in the postoperative period following cardiac surgery when compared to preoperative values. In particular, an increase in postoperative creatinine levels of 26.5 *mol/L when compared to preoperative creatinine values is considered as AKI.

Secondary outcome

Highest serum creatinine level measured in the first 72 postoperative hours following surgery. Postoperative urine production, serum urea levels, creatinine clearance, glomerular filtration rate, biomarkers for acute renal injury, prevalence of postoperative renal replacement therapy, nadir oxygen delivery (DO2), DO2/VCO2 ratio, sublingual microcirculatory perfused vessel density and perfused boundary region, and sublingual oxygen saturation levels.

Study description

Background summary

In the Netherlands, about 14,000 patients yearly undergo cardiac surgery with cardiopulmonary bypass (CPB), which might be associated with postoperative complications like renal dysfunction/acute kidney injury. Previous studies suggest that pulsatile blood flow during CPB has protective effects on the renal function. In high-risk patients, pulsatile blood flow improved microcirculatory and renal perfusion and reduced postoperative elevations in creatinine in patients undergoing coronary artery bypass graft surgery. Others however found no beneficial effects of pulsatile blood flow during CPB on

postoperative renal function. Due to the conflicting evidence we aim to investigate whether pulsatile blood flow during CPB might be beneficial for postoperative renal function. We hypothesize that pulsatile blood flow during CPB reduces the relative increase in perioperative creatinine levels after cardiac surgery in patients with preoperative renal dysfunction. We also aim to investigate possible underlying mechanisms by focusing on the level of microcirculatory perfusion and oxygenation, the delivery and consumption of oxygen in the systemic circulation and CO2 production in patients subjected to pulsatile or non-pulsatile flow.

Study objective

Does pulsatile blood flow during cardiopulmonary bypass lead to a reduction in the average increase in postoperative creatinine levels in patients with preoperative renal dysfunction when compared to non-pulsatile blood flow?

Study design

Randomized controlled multicenter trial

Intervention

Pulsatile flow during cardiopulmonary bypass

Study burden and risks

We hypothesize that pulsatile blood flow might be beneficial for perioperative renal function, and therefore patients may benefit from inclusion in this study group. The use of non-pulsatile or pulsatile blood flow is part of routine cardiosurgical procedures and not associated with a risk for the patient.1 A total of 120 ml of extra blood will be drawn from an existing intra-arterial line while the patient is under anesthesia. The intra-arterial line is part of routine clinical care in cardiac surgery, and will therefore not add up to patient discomfort in the present study. Microscopic imaging or reflectance spectroscopy of the microvasculature by means of the GlycoCheck or O2C is a noninvasive measurement. DO2 and VCO2 levels are automatically recorded by an integrated monitor in the heart-lung machine device.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117

Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Informed consent
- Adult subjects (age 18-90 years) undergoing elective cardiac surgery with cardiopulmonary bypass
- Patients with preoperative renal dysfunction (either eGFR <55 mL/min/1.73m2 at one measurement, or an eGFR <60 mL/min/1.73m2 for more than three months) or patients with diabetes mellitus and an eGFR <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)
- BSA > 2.3 m2

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2014
Enrollment:	294
Type:	Actual

Medical products/devices used

Generic name:	Heart-Lung Machine with Heartlink monitor with laminar or pulsatile blood flow
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-04-2018
Application type:	Amendment
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

ID: 21086
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50135.029.14
OMON	NL-OMON21086