The Goal dIrected perFusion Trial, a multi-center, prospective, randomized, controlled study.

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The present study is designed to verify the hypothesis that a strategy based on a goal-directed perfusion, aimed to avoid a nadir DO2 below the critical threshold, is effective in limiting the postoperative AKI rate.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON42063

Source
ToetsingOnline

Brief title
GIFT study

Condition

- Cardiac disorders, signs and symptoms NEC
- Renal disorders (excl nephropathies)

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,Sorin Biomedica CRM

SRL

Intervention

Keyword: blood transfusion, kidney injury, oxygen delivery, perfusion

Outcome measures

Primary outcome

Incidence of AKI, defined according to the AKIN criteria (9) as:

AKI stage 1: peak postoperative serum creatinine > 1.5 x baseline, within the first 48 hours after surgery.

AKI stage 2: peak postoperative serum creatinine > 2.0 x baseline, within the first 48 hours after surgery (AKI stage 3 will be incorporated in the AKI stage 2 group).

Any AKI: stage 1 or higher

Peak serum creatinine: within the first 48 postoperative hours.

Diagnosis of AKI must be reached within the first 48 hours after surgery, but staging may require a longer time (up to 7 days after surgery).

Secondary outcome

Length of ICU stay (days)

Transfusion (PRCs) rate and amount of PRCs units transfused

Major morbidity (according to STS): mechanical ventilation > 48 hours, AKI stage 2, surgical revision, mediastinitis, stroke.

Operative (in-hospital) mortality

Study description

Background summary

Previous studies (1-5) have demonstrated that oxygen delivery (DO2) and carbon dioxide production (VCO2) during cardiopulmonary bypass (CPB) are associated with renal outcome in cardiac surgery. The critical value for DO2 is around 262 * 272 mL/min/m2, and the correspondent critical value of DO2/VCO2 ratio is around 5.0.
Patients with nadir DO2 and DO2/VCO2 ratio below these critical levels have an increased incidence of acute kidney injury (AKI) after cardiac operations.
These observations offer an interpretation for the well-known deleterious effects of excessive hemodilution during CPB, supported by many studies where an association between nadir hematocrit (HCT) on CPB and bad outcomes (especially renal) was found (6-8). It is reasonable to hypothesize that a low oxygen delivery may determine an ischemic damage to the kidney, that due to its peculiar circulation is particularly susceptible to a decrease in the oxygen supply.
However, there is no evidence that a strategy directed towards the specific goal of avoiding critical values of DO2 during CPB may actually decrease the postoperative AKI rate.

Study objective

The present study is designed to verify the hypothesis that a strategy based on a goal-directed perfusion, aimed to avoid a nadir DO2 below the critical threshold, is effective in limiting the postoperative AKI rate.

Study design

Multicenter, international, prospective, randomized and controlled study.

Intervention

Patients will be randomly allocated to the Control or the GDP group.
Randomization will be performed locally at each participating Institution, using computer-generated schemes. The patients in control Group will be treated according to the local standards. The patients in GDP group will be treated according to the GDP.

Details of the GDP protocol:
The main intervention to achieve the target value of DO2 is increasing the pump flow. Additional interventions include hemofiltration to increase the HCT.

Transfusion protocol:
1. During CPB: Transfusions are mandatory below a HCT of 18%. Transfusions are generally prohibited for an HCT > 21%. However, based on the individual judgement that the patient is actually in need for packed red cells,

transfusions are allowed between an HCT of 22% and 24%. In this case, this will be considered as a protocol violation, but the patient will not be withdrawn. Transfusions are always prohibited for an HCT > 24%.
2. After CPB:
HCT < 18%: packed red cells are mandatory
HCT between 19% and 23%: packed red cells are allowed
HCT between 24% and 30%: packed red cells generally prohibited, but admitted based on physician*s judgement. This represents a protocol violation. In this case, this will be considered as a protocol violation, but the patient will not be withdrawn.
HCT > 30%: packed red cells are prohibited.

Study burden and risks

Perfusion by the heart-lung machine based on the oxygen supply levels does not involve any risk for the patient. The intervention takes place while the patient is under anesthesia, which is therefore not associated with a burden for the patient.

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

Adult patients
Patients undergoing cardiac surgery with expected bypass time of 90 minutes or longer

Exclusion criteria

severe chronic renal failure
moderate-severe anemia (hematocriet < 32%)
emergency surgery
CPB temperature < 32 degree Celcius

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2015
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Bloodgas monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-04-2015
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	NL50588.029.14