# The effect on cerebral oxygenation of retrograde autologous priming of the CPB circuit in cardiac surgery patients: a Randomized Controlled Trial

Published: 12-12-2013 Last updated: 23-04-2024

Primary Objective: The primary objective of this study is to determine whether RAP limits the degree of hemodilution and limits prolonged intraoperative cerebral desaturation during during CPB, compared to the conventional priming method. Prolonged...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

# Summary

### ID

NL-OMON38712

**Source** ToetsingOnline

#### **Brief title**

The effect on cerebral oxygenation of RAP of the CPB circuit

### Condition

Cardiac therapeutic procedures

**Synonym** cognition, regional cerebral oxygenation

**Research involving** 

Human

### **Sponsors and support**

#### Primary sponsor: Amphia Ziekenhuis

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Source(s) of monetary or material Support: Amphia Ziekenhuis; Wetenschapsbudget

### Intervention

Keyword: cerebral oxygenation, cognition, retrograde autologous priming

### **Outcome measures**

#### **Primary outcome**

The primary study parameter of this study is prolonged intraoperative cerebral desaturation and will be assessed by rSO2 desaturation score50. rSO2 desaturation score50 > 3000 is associated with increased risk of cognitive decline (1). Formula described by Slater et al. : rSO2 score = 50% rSO2 - current rSO2 (%) x time (s) will be used to calculate the rSO2 score; from the intraoperative cerebral oximetry data (1).

#### Secondary outcome

List of secondary study parameters:

- CODE (number and duration)
- rSO2 during CPB
- Subjective Cognition Failure Questionnaire (one day preoperatively, 3 months

after randomization, 6 months after randomization)

- Hct/ Hb during CPB
- o Nadir Hb, Hct intraoperative, during postoperative ICU & hospital stay
- Surgical re-explorations
- Length of ICU stay
- Length of hospital stay
- Hours to detubation
- Neurological events
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- Fluid balance
- Administration of vasoactive drugs during CPB
- sVO2 during CPB

# **Study description**

### **Background summary**

In cardiac surgery, prolonged intraoperative cerebral desaturation is associated with postoperative cognitive dysfunction (POCD) (1, 2), characterised as impairment in attention, cognition, recognition, orientation, memory and learning. It may result in prolonged hospitalisation, increased morbidity and mortality, while it has an adverse impact on quality of life after surgery.

We also know that cerebral perfusion during cardiopulmonary bypass (CPB) is influenced by a numbers of factors, including hemodilution.

Retrograde autologous priming (RAP) is a technique where, the patient\*s own circulating blood partially replaces the priming solution in the CPB, which results in less hemodilution and less transfused red blood cells compared to the conventional CPB priming method in cardiac surgery patients. In their retrospective study Hwang et al. assessed the regional cerebral oxygenation (rSO2) by near-infrared spectroscopy (NIRS) and concluded that RAP limited the degree of hemodilution and limits the deterioration in the rSO2 with a mean difference of 5% points during CPB, compared to the conventional priming method (4).

Different studies have shown a significant association between intraoperative oxygen desaturation, assessed by rSO2 desaturation score, and POCD (1). Slater et al. showed that patients with an rSO2 desaturation score50 > 3000 had a significantly higher risk of postoperative cognitive decline (OR = 2.22, p = 0.024) (1). However, because of the absence of prospective studies, the effect on regional cerebral oxygenation by RAP still remains unclear. We therefore hypothesize that RAP limits the degree of hemodilution and thereby limits the prolonged intraoperative cerebral desaturation, assessed by the incidence of rSO2 desaturation score50 > 3000.

### Study objective

Primary Objective:

The primary objective of this study is to determine whether RAP limits the degree of hemodilution and limits prolonged intraoperative cerebral desaturation during during CPB, compared to the conventional priming method. Prolonged intraoperative cerebral desaturation will be assessed by rSO2

desaturation score50. rSO2 desaturation score50 > 3000 is associated with increased risk of cognitive decline (1). We hypothesize that RAP limits the degree of hemodilution and thereby limits the incidence of rSO2 desaturation score50 > 3000 with a relative difference of 50%. Formula described by Slater et al. : rSO2 score = 50% rSO2 - current rSO2 (%) x time (s) will be used to calculate the rSO2 score; from the intraoperative cerebral oximetry data.

#### Secondary Objective(s):

The secondary objective is to compare the amount of cerebral oxygenation desaturation episodes (CODE) and their duration. CODE will be defined by a reduction of 20% baseline value of at least one minute or an absolute reduction of 50%.

Also, the difference in rSO2 will be assessed at six time points (from a period of 5 minutes): T1 before induction of general induction of general anesthesia; T2 after induction of general anesthesia when vital signs are stable; T3 after initiation CPB; T4 after cross clamping the aorta; T5 after removal of cross-clamp; T6 after weaning of CPB.

Furthermore, cognition will be evaluated at baseline (one day preoperatively), three and six months after randomization by the Subjective Cognitive Failure Questionnaire (CFQ).

As secondary objective, Hematocrit (Ht) during CPB, haemoglobin level (Hb) during CPB, fluid balance, administration of vasoactive drugs, surgical re-explorations, length of intensive care unit (ICU) stay, time to detubation, mixed venous oxygen saturation (sVO2) during CPB, and postoperative neurological events will be compared.

### Study design

Design of the study is a Randomized Controlled Trial. By means of a computer-generator 1:1 randomization table, subjects will be divided in the RAP group or the Control group. In the RAP group, the patient\*s own circulating blood will partially replace the priming solution in the CPB (which can be exactly measured). In the Control group the conventional priming method will be used.

### Intervention

The subjects who are divided in the RAP group, the retrograde autologous priming technique will be used, where the patient\*s own circulating blood partially will be replaced by the priming solution in the CPB. In the Control group the conventional priming method will be used.

The RAP method is based on the study of Hwang et al. In RAP, the priming solution is partially replaced by the patient\*s own circulating blood, before initiation of CPB. After arterial cannulation of the aorta ascendens (DLP® arterial cannula straight or curved, Medtronic Inc®, Minneapolis, MN, USA) the priming volume in the arterial line is replaced by the patient\*s own blood

through gravity drainage, the priming solution is pushed in a blood transfer bag. After venous cannulation (Dual-stage venous drainage cannula 36/51 fr, Medtronic Inc® MC2) a clamp is placed on the arterial line. After starting venous drainage, the priming volume of the venous line is pumped into the blood transfer bag and replaced by patient\*s own blood. When approximately 400 ml of priming volume is displaced into the bag, the line to the bag will be closed and the clamp will be removed from the arterial line. Thereafter, de cardiopulmonary bypass is started. After initiation of cardiopulmonary bypass the priming volume is approximately 900 ml.

In case of the conventional priming method, the priming volume of the arterial and venous line will not be replaced by patient\*s own blood. The priming volume of cardiopulmonary bypass is 1300 ml in the conventional method

#### Study burden and risks

As there are no risks involved there will be no intermediate security check.

# Contacts

**Public** Amphia Ziekenhuis

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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#### Age

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

### **Inclusion criteria**

- Gender; male/ female
- Age: >= 70 year
- Elective cardiac surgical patients who underwent combined procedure
- o Coronary artery bypass graft (CABG) surgery combined with valve surgery:
- o CABG/ Aortic valve replacement (AVR)
- o CABG/ Mitral valve replacement (MVR)
- o CABG/ Mitral valve repair (MPL)
- o CABG/ Tricuspid valve replacement (TVR)
- o CABG/ Tricuspid valve repair (TPL)

# **Exclusion criteria**

- Elective cardiac surgical patients who underwent single procedure
- o Coronary artery bypass graft (CABG) (conventional, E.CCO)
- o Aortic valve replacement (AVR) (conventional, minimal invasive) o Bentall
- o Combined procedure (eg. MVR/AVR, AVR/Maze)
- o Tricuspid valve replacement (TVR) / Tricuspid valve repair (TPL)
- o MVR/MPL (conventional, minimal invasive, Port Access Surgery)
- o Maze (minimal invasive, via Thoracoscopy)
- o off-pump procedures
- o re-operation
- o Other
- Emergency operations
- Methylene blue administration

# Study design

# Design

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

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#### Primary purpose: Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2014
Enrollment:	220
Туре:	Actual

# **Ethics review**

Approved WMO	12-12-2013
Date.	12-12-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	06-07-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

# **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 CCMO **ID** NL46578.015.13

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