Influence of Variations in Systemic Blood Flow and Blood Pressure on Cerebral Oxygenation during Cardiac Surgery.

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The aim of this study is to investigate whether patients on cardio-pulmonary bypass have intact autoregulation or not, and to investigate whether systemic flow or MAP has the greatest effect on cerebral oxygenation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32638

Source
ToetsingOnline

Brief title
Influence of Blood Flow and Blood Pressure on Cerebral Oxygenation

Condition

- Other condition

Synonym
The influence of variations in blood pressure and variations in blood flow on cerebral autoregulation

Health condition

Mensen aan een extra-corporeel circuit

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood Flow, Blood Pressure, Cerebral Oxygenation, Near-infrared spectroscopy (NIRS)

Outcome measures

Primary outcome

The relationship between variations in blood pressure and blood flow on the one

hand, and cerebral oxygenation on the other hand.

Secondary outcome

The effect of phenylephrin and vasopressin on cerebral oxygenation

Study description

Background summary

This study emphasizes on the influence of changes in systemic flow and systemic mean arterial blood pressure (MAP) during cardio pulmonary bypass (CPB) on cerebral oxygenation assessed by transcranial near-infrared spectroscopy (NIRS). We want to determine whether variations in systemic flow, variations in MAP or variations in both parameters at the same time have the greatest impact on the cerebral autoregulation.

Study objective

The aim of this study is to investigate whether patients on cardio-pulmonary bypass have intact autoregulation or not, and to investigate whether systemic flow or MAP has the greatest effect on cerebral oxygenation.

Study design

To assess cerebral oxygenation, we use NIRS (near-infrared spectroscopy). We measure rSO2 per-operatively in patients undergoing thoracic surgery with the use of CPB (heart-lung machine). When patient is on CPB, we start our

interventions, meaning that we variate CPB-flow at a constant blood pressure and vice versa.

Intervention

When the patient is on cardiopulmonary bypass, we will modify the systemic blood pressure and/or systemic blood flow while measuring the cerebral oxygenation. We have one series of measurements during which the systemic blood pressure is modified, and one series of measurements during which the systemic flow is modified. Our measurements will be finished within one hour, this will not exceed the normal duration of extracorporeal circulation, which is 90-120 minutes. Therefore, we will not prolong the surgical procedure.

Before each intervention, we record a baseline during two minutes. During this baseline recording, no modifications are made. When the baseline value is obtained, we perform one of the interventions named below. This process is repeated until all seven interventions are completed.
During surgery, mean arterial pressure is maintained at approximately 80 mmHg. With our interventions, we induce a raise and a reduction in blood pressure of approximately 20 mmHg. This is within the normal range during operations. Systemic flow is regulated by the CPB-operator. Normally CPB-flow is maintained at 2,6 L/m2. With our interventions, we raise this to 3,1 L/m2 and lower this to 2,1 L/m2. This is also within the normal range.

Our interventions are:
Modifications in blood pressure:
* Increase of the systemic blood pressure by approximately 20 mmHg, using phenylephrine (an alpha-receptor dependent vasoconstrictor)
* Increase of the systemic blood pressure by approximately 20 mmHg, using vasopressin (an alpha-receptor independent vasoconstrictor)
* Reduction of the systemic blood pressure by approximately 20 mmHg, using sodiumnitroprusside

Modifications in blood flow:
* Reduction of the blood flow by 0.5l/m2
* Reduction of the blood flow by 0.5l/m2, while using phenylephrine to maintain systemic blood pressure
* Increase of the blood flow by 0.5l/m2
* Increase of the blood flow by 0.5l/m2, while maintaining a constant systemic blood pressure using sodiumnitroprusside

Study burden and risks

The investigated interventions are within the physiological range of variations. No adverse effects of changes of the hemodynamics within the proposed limits are known. Anesthesia and surgical technique will be applied

according to standard procedures.

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

-patient is older than 18 years
-patient is scheduled to undergo elective cardiac surgery with the use of an cardiopulmonary bypass.
-informed consent

Exclusion criteria

-patient under 18 years old
-patient older than 70 years
-Carotid artery stenosis (examination before surgery with echo-Dopplergraphy)
-emergency operations
-severe COPD
-no informed consent
-SaO2 < 90% at room temperature
-diabetes
-Renal falure
-Brain pathology (CVA) in history

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

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	NL29879.018.09