Blood Pressure and Cardiac Output - the influence on cerebral perfusion during cardiopulmonary bypass.

Published: 30-07-2014
Last updated: 20-04-2024

To study the influence of systemic blood flow and mean arterial pressure on cerebral blood flow in patients undergoing on-pump cardiac surgery.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40836

Source
ToetsingOnline

Brief title
Parameters of cerebral perfusion

Condition

- Other condition

Synonym
cerebral autoregulation, oxygen regulation of the brain

Health condition

patienten aan de cardiopulmonale bypass

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Blood flow, Blood pressure, Cerebral perfusion, Near InfraRed Spectroscopy (NIRS)

Outcome measures

Primary outcome

Primary endpoint is the cerebral perfusion measured by the regional cerebral

oxygen saturation (rSO2) and the mean velocity of bloodflow in the middle

cerebral artery (Vmca).

Secondary outcome

not applicable

Study description

Background summary

A jeopardized cerebral blood flow (CBF) for a few minutes* results in irreversible cerebral tissue damage. Therefore, the CBF is autoregulated implying that CBF remains constant despite changes in cerebral perfusion pressure. Since the 1970s, Near Infra-Red spectroscopy (NIRS) derived frontal lobe oxygenation (rSO2) and flow velocity of the middle cerebral artery (Vmca) measured by transcranial doppler (TCD) can be used continuously and non-invasively, as a derivative for CBF. These monitoring techniques are used extensively and in the case of a decreasing rSO2, various algorithms have been proposed to optimize rSO2. One of the first steps in the algorithm is to increase blood pressure by administrating an α1-receptor mediated vasopressor like phenylephrine. However, several studies recently described that the rSO2 decreased after phenylephrine administration. It remains unknown why rSO2 decreased, but it could be a result of the α1-receptor mediated decline in cardiac output (CO). This hypothesis is supported by the finding that in patients on CPB, i.e. with constant CO, the rSO2 only decreased with 3% after administering phenylephrine in comparison to a 10% decline in rSO2 in non-cardiac surgery. It therefore still remains unclear whether rSO2 is (more)

dependent on blood pressure or on CO. Therefore our aim is to determine whether cerebral perfusion is most dependent on cardiac output or on mean arterial pressure in patients undergoing cardiac surgery with the use of CPB.

Study objective

To study the influence of systemic blood flow and mean arterial pressure on cerebral blood flow in patients undergoing on-pump cardiac surgery.

Study design

Cross-over design

Intervention

5 interventions which will include raising mean arterial pressure (MAP) by administering 100µg phenylephrine, increasing and decreasing cardiac output by adjusting roller pump flow or a combination of the previous.

Interventions pre-cardiopulmonary bypass
(1) An increase in MAP of approximately 20 mmHg by administrating 100µg phenylephrine.

Interventions during cardiopulmonary bypass
Modifications in blood pressure:
(2) An increase in MAP by administrating 100µg phenylephrine while maintaining roller pump flow constant.

Modifications in systemic flow:
(3) A modification of roller pump flow to achieve the CO measured at intervention (1) meaning: preCPB after the bolus of 100µg phenylephrine.
(4) A modification of roller pump flow as in (3) together with a bolus of 100µg phenylephrine to increase MAP.
(5) An increase in roller pump flow aiming for a 20 mmHg increase in MAP.

Study burden and risks

The burden and risks of participating in this study are neglible because all modifications will be in the physiological range. Phenylephrine used in this study will be used within its indication and is approved by the Food and Drug Administration (FDA).
There will be no time burden since all the investigations can be done during cardiopulmonary bypass time. There will be no follow up.

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

- age over 18 years
- undergoing cardiopulmonary bypass for Coronary Artery Bypass Grafting (CABG)/Valve replacement/repair
- having an appropriate temporal bone window for TransCranial Doppler monitoring

Exclusion criteria

- requiring hypothermia during surgery
- requiring emergency surgery
- having a contraindication for phenylephrine
- having known brain pathology (e.g. Cerebral Vascular Accident (CVA) of increased

intracranial pressure)
- having a history of severe carotid artery stenosis

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	32
Type:	Anticipated

Ethics review

Not approved

Date:	30-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL48417.041.14