

# Cerebral oxygenation during changes in vascular resistance and flow in patients on cardiopulmonary bypass

<b>Submission date</b> 12/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/01/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study is performed in patients having cardiac (heart) surgery with the use of a heart-and-lung machine. Blood supply to the brain is normally regulated by a mechanism called 'cerebral autoregulation'. Cerebral autoregulation means that the body preserves blood supply to the brain despite wide variations in blood pressure. A way of assessing blood supply to the brain is measuring the oxygen content of a small part of the brain tissue using near-infrared spectroscopy. This is a non-invasive method where two adhesive pads are placed on the patient's forehead. These pads send out light at a frequency close to the infrared part of the electromagnetic spectrum. This light can penetrate the skull and is reflected by the brain tissue. By analysing the reflected light, the oxygen saturation (i.e. the amount of oxygen present) of a small portion of the brain can be measured. Recent studies investigated the effects of different blood-pressure-increasing medications on the cerebral oxygenation (oxygen levels in the brain) and found that after a dose of the drug phenylephrine, blood pressure was raised, but cerebral oxygenation decreased. A possible mechanism for this could be that phenylephrine slightly increases the resistance of blood vessels to the brain and thus decreasing the blood flow; this potentially leads to a decrease in the oxygenation of brain tissue. In this study we want to investigate this hypothesis further by performing several blood-pressure-increasing manoeuvres in patients connected to a heart-and-lung machine during cardiac surgery. These include administration of two different substances widely used in standard care of anaesthesia to raise blood pressure (phenylephrine and vasopressin) and an increment (increase) in the heart-and-lung machine pump flow (to simulate a rise in cardiac output). These different manoeuvres will all raise blood pressure, but might have different effects on cerebral oxygenation. The results of this study will help to get a better understanding of physiological (normal) mechanisms that control blood supply to the brain.

### Who can participate?

Adults aged 18-70 having cardiac surgery requiring a heart-and-lung machine.

### What does the study involve?

During surgery, the blood pressure of all the participants are raised in three different ways in a

randomized order. The first method of raising blood pressure is  $\alpha$ 1-mediated, with phenylephrine, while CPB (cardiopulmonary bypass)-flow is clamped. The second method is non- $\alpha$ 1-mediated, with vasopressin while CPB-flow remains unchanged. The third method involve increasing CPB-flow. Cerebral oxygenation and arterial blood pressure is measured for each participant before and after each method is applied.

What are the possible benefits and risks of participating?  
Not provided at time of registration.

Where is the study run from?  
Academic Medical Center AMC (Netherlands)

When is the study starting and how long is it expected to run for?  
January 2010 to June 2013

Who is funding the study?  
Academic Medical Center, AMC Amsterdam (Netherlands)

Who is the main contact?  
Mr Niek Sperna Weiland

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
Protocol revision 2.3; nov 23, 2009. NL29879.018.09. MEC 09/280.

# Study information

## Scientific Title

Cerebral oxygenation during changes in vascular resistance and flow in patients on cardiopulmonary bypass: a randomized cross over trial

## Study objectives

Phenylphrine causes  $\alpha$ 1-receptor mediated cerebral vasoconstriction

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medisch Ethische Toetsingscommissie Academisch Medisch Centrum, ref: 09/280

## Study design

Single center interventional study

## Primary study design

Interventional

## Secondary study design

Randomised cross over trial

## Study setting(s)

Hospital

## Study type(s)

Other

## Participant information sheet

Participant information available in Dutch only. Not available in web format, please use the contact details below to request a copy of the patient information sheet.

## Health condition(s) or problem(s) studied

Physiology of brain perfusion.

## Interventions

During the cardiopulmonary bypass-phase of cardiac operations, when the patients were hemodynamically stable and a CPB-flow was  $2.6 \text{ L} \cdot \text{m}^{-2} \cdot \text{min}^{-1}$  subjects underwent three interventions in randomized order. During these interventions no other hemodynamic interventions were performed.

1. Mean arterial blood pressure (MABP) was raised by increasing CPB-flow by  $0.5 \text{ L} \cdot \text{m}^{-2} \cdot \text{min}^{-1}$  for five minutes
2. MABP was raised  $\approx 15 \text{ mmHg}$  by an  $\alpha$ 1-mediated increase in SVR with a PE bolus of 50-150  $\mu\text{g}$  while CPB flow remained unaltered at  $2.6 \text{ L} \cdot \text{m}^{-2} \cdot \text{min}^{-1}$
3. MABP was increased  $\approx 15 \text{ mmHg}$  by a V1-receptor mediated increase in SVR with a VP bolus of 0.1 - 0.4 IU while CPB flow remained unaltered at  $2.6 \text{ L} \cdot \text{m}^{-2} \cdot \text{min}^{-1}$

## Intervention Type

Mixed

**Primary outcome measure**

Cerebral oxygenation before and after each intervention.

**Secondary outcome measures**

Arterial blood pressure before and after each intervention.

**Overall study start date**

01/01/2010

**Completion date**

14/06/2013

## **Eligibility**

**Key inclusion criteria**

1. Age 18-70 years
2. Patients scheduled for elective cardiac surgery (CABG, aortic valve repair, mitral valve repair or combinations of the former), using mil hypothermic cardiopulmonary bypass.
3. Written informed consent present

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

10

**Key exclusion criteria**

1. Age  $\leq 18$  years
2. Emergency operations
3. Brain pathology in history (CVA)
4. Severe carotid artery stenosis (if no data is available, an echo-Doppler will be performed by the anesthesiologist after induction of anesthesia, prior to surgery)
5. Severe COPD
6. Absent informed consent

7. SaO<sub>2</sub><90% at room temperature

8. Diabetes

9. Kidney failure

**Date of first enrolment**

23/03/2010

**Date of final enrolment**

14/06/2013

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Academic Medical Center AMC**

Meibergdreef 9

Amsterdam-Zuidoost

Netherlands

1105 AZ

## **Sponsor information**

**Organisation**

Academic Medical Center AMC

**Sponsor details**

Meibergdreef 9

Amsterdam Zuidoost

Netherlands

1105AZ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.amc.nl>

**ROR**

<https://ror.org/03t4gr691>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Academic Medical Center, AMC Amsterdam (Netherlands)

## Results and Publications

**Publication and dissemination plan****Intention to publish date**

31/12/2015

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2017	18/01/2019	Yes	No