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

Submission date
12/10/2015

Recruitment status
No longer recruiting

Registration date
22/10/2015

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 a 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 α1-mediated, with phenylephrine, while CPB (cardiopulmonary bypass)-flow is clamped. The second method is non-α1-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 α1-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 L•m-2•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 L•m-2•min-1 for five minutes
2. MABP was raised ≈15 mmHg by an α1-mediated increase in SVR with a PE bolus of 50-150 µg while CPB flow remained unaltered at 2.6 L•m-2•min-1
3. MABP was increased ≈15 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 L•m-2•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 ≤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. SaO2<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?
Results article	results	01/01/2017	18/01/2019	Yes	No