Measuring static and dynamic cerebral autoregulation intraoperatively in volunteers at different steady-state MBP.

Published: 03-01-2019
Last updated: 11-04-2024

Establish relationship between static and dynamic CA during general intravenous or inhalational anaesthesia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46058

Source
ToetsingOnline

Brief title
Measuring cerebral autoregulation intraoperatively in volunteers.

Condition

- Central nervous system vascular disorders

Synonym
Cerebral autoregulation, Regulation of cerebral blood flow

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anaesthesia-induced patients, Cerebral autoregulation, Dynamic cerebral autoregulation, Static cerebral autoregulation

Outcome measures

Primary outcome

Differences in MAP, cerebral oxygenation, MCAV and dynamic and static cerebral

autoregulation indices during blood pressure modifications.

Secondary outcome

nvt

Study description

Background summary

Cerebral autoregulation (CA) is the physiological mechanism that maintains cerebral blood flow (CBF) more or less constant despite variations in blood pressure and therefore safeguards cerebral metabolic needs during hypotension. This implies that cerebral vessels dilate during hypotension (directing blood flow towards the brain) and constrict during hypertension (protecting the brain for hyperperfusion). Thus, if the efficacy of CA is compromised, the risk of cerebral hypoperfusion increases when blood pressure is low, for example during anaesthesia.
To quantify the integrity of CA is challenging since simultaneous blood pressure and CBF measurements are required across a wide range of blood pressures Determination of blood pressure is simple but gold standard quantification of CBF is highly invasive and time consuming.

The development new techniques such as finger photoplethysmography and the transcranial Doppler enabled non-invasive, real-time, recording of systemic blood pressure and blood flow velocity (V) in the middle cerebral artery (MCA). This simplified the measurements on CA considerably. Furthermore, the concept of dynamic CA was introduced. Contrary to static CA, this describes how quickly the cerebral vessels react to a change in blood pressure to normalise CBF

In this proposal, we aim to clarify the (limits of) CA in the non-cardiothoracic surgical population. To study this, we monitor brain perfusion indices and blood pressure (both non-invasively) in a cohort of

patients under general anaesthesia.

We aim to record brain perfusion indices at MAP 60, 70, 80, 90 and 100 mmHg. The value of MAP 60 mmHg is the accepted lower limit during anaesthesia and MAP 100 mmHg corresponds to the normal awake value (RR 120/80). Therefore, all these values are within the normal physiological range. To correct for different anaesthesia regimens, we randomise patients to receive either inhalational or intravenous anaesthesia. Both techniques are accepted ways of administering general anaesthesia and are both employed on a daily basis in our hospital (depending on the preference of the anaesthesiologist).

Study objective

Establish relationship between static and dynamic CA during general intravenous or inhalational anaesthesia.

Study design

We propose a single centre, open label trial in ASA-I or II intraoperative patients. Patients will be recruited from the elective operating schedule. After induction of anaesthesia, we perform measurements on cerebral perfusion. After data collection, the study is terminated intraoperatively. There will be no follow-up postoperatively.

Study burden and risks

Test subjects will be investigated while undergoing planned surgery. The entire investigation will take place while under anaesthesia. This means the test subjects will not experience significant extra burden from the test measurements. Conversely, they will not have additional benefits from the investigation.

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

ASA-I or ASA-II, willing and able to give written informed consent, scheduled for elective, non-cardiothoracic surgery under general anaesthesia and age 18 years and above.

Exclusion criteria

Patient related
* Unable/ unwilling to participate
* ASA-III or higher
* Age < 18 years
* History of: uncontrolled hypertension, diabetes, Parkinson*s disease, uncontrolled cardiac arrhythmia, Pure autonomic failure (formerly called idiopathic orthostatic hypotension), Multiple system atrophy with autonomic failure (formerly called Shy-Drager syndrome), Addison*s disease and hypopituitarism, pheochromocytoma, peripheral autonomic neuropathy (e.g., amyloid neuropathy, idiopathic autonomic neuropathy), known cardiomyopathy, extreme left ventricle hypertrophy or ejection fraction < 30%, proven or suspected allergy for any of the medication used during induction of anaesthesia, malignant hyperthermia.
* Unability to record transcranial Doppler ultrasound due to anatomical variance (~5% of population)
* Contra-indications for intravenous or inhalational anaesthesia.
Surgery related
* Day case surgery
* Laparoscopy with CO2 insufflation
* Extreme positioning during surgery (head-down/up tilt, lateral decubitus position, prone)

* Surgery < 60 minutes.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2019
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	19-03-2019
Application type:	Amendment
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	NL66973.018.18