

ANESTHESIOLOGICAL EFFECTS ON CEREBRAL MICROVASCULATURE

Published: 06-02-2024

Last updated: 07-04-2024

To assess the effects of anesthetics on local (cerebral) microvascular parameters in craniotomy patients. Secondary objective: To assess the effects of anesthetics on systemic (sublingual) microvascular parameters in craniotomy patients.

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

Summary

ID

NL-OMON56513

Source

ToetsingOnline

Brief title

ANESTHESIA AND CEREBRAL MICROVASCULATURE

Condition

- Central nervous system vascular disorders

Synonym

cerebrovascular microcirculation; brain's blood vessels

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anesthesia, Cerebrovascular, Glycocalyx, Microcirculation

Outcome measures

Primary outcome

The primary study parameter is perfused boundary region ((PBR), a continuous variable in expressed micrometers.

PBR is presented as mean (\pm standard deviation) if normally distributed, and as median (range) if non-normally distributed.

Differences between the groups will be calculated using t-test or Mann-Whitney U-test.

Differences intra-individually before and after induction of general anesthesia will be calculated using t-test or Mann-Whitney U-test.

Differences intra-individually between sublingual and cortical measurements will be calculated using t-test or Mann-Whitney U-test.

Spearman rank correlation coefficient and uni- and multivariate regression analysis will be used to assess correlations between clinical (8.3.3. other study parameters) and PBR values.

Missing data will be replaced by a mean or median value. p-value <0.05 is considered statistically significant.

Given the pilot design and the explorative character of the study, the described statistics are primarily descriptive statistics, including testing the null-hypothesis and all microvascular properties.

Secondary outcome

Microvascular properties are expressed in different dimensions:

- Perfused diameter (μm)
- RBC velocity ($\mu\text{m/s}$)
- perfused vessel density (mm/mm^2)
- Capillary blood volume (μm^3)
- Capillary recruitment capacity (%)

Sublingual microvascular parameters will be compared between groups (anesthesia inhalation; anesthesia intravenous; awake) using the two-tailed student's t-test or Mann-Whitney U-test or chi-square test.

Cortical microvascular parameters will be compared between groups (anesthesia inhalation; anesthesia intravenous; awake) using t-test or Mann-Whitney U-test or chi-square test.

Sublingual microvascular parameters intra-individually before and after induction of general anesthesia will be calculated using t-test or Mann-Whitney U-test or chi-square test.

Cortical microvascular parameters intra-individually before and after induction of general anesthesia will be calculated using t-test or Mann-Whitney U-test or chi-square test.

Sublingual and cortical microvascular parameters intra-individually will be calculated using t-test or Mann-Whitney U-test or chi-square test.

P-value <0.05 is considered statistically significant.

To correct for multiple testing in comparisons of microcirculation variables per-diameter class we use the false discovery rate (FDR) approach of Benjamini, Krieger and Yekutieli, setting a q value < 0.05 as significant.

When results are not normally distributed, Mann-Whitney-U test will be performed.

Study description

Background summary

Cerebral microcirculation plays a significant role in various cerebral diseases. Sidestream darkfield (SDF) videomicroscopy allows assessment of the microcirculation in vivo. The SDF camera is either used sublingually, providing assessment of the systemic microcirculation in many different disorders, or directly on the brain in patients undergoing a craniotomy for various different indications. This last technique allows us to study microvascular properties of the brains of our craniotomy patients. Craniotomies are usually carried out under general anesthesia, but are performed in awake patients as well. Anesthetics are known to affect hemodynamic and microvascular properties. To further investigate the role of microcirculation alterations in the pathophysiology of neurological disorders, we first need to establish what part of the effects can be attributed to anesthesia. We hypothesize that the cerebrovascular microcirculation is affected by different types of anesthesia, wherein general anesthesia has a greater detrimental effect compared to awake surgery.

Study objective

To assess the effects of anesthetics on local (cerebral) microvascular parameters in craniotomy patients.

Secondary objective: To assess the effects of anesthetics on systemic (sublingual) microvascular parameters in craniotomy patients.

Study design

Observational cohort study with pilot design.

Study burden and risks

Given the burden of disease for oncology patients and patients with neurological conditions, that is the consequence of our lack of pathophysiological knowledge, and given the fact that our proposed study, which is non-invasive and extremely low risk/low burden for the patient, will give us unique information on the pathophysiology of microvascular disease, we think it is justified to conduct the study. The sublingual measurements take place during preparation of surgery, or during surgery itself and will not delay the procedure, while the cortical measurement may only delay the procedure by 15 minutes (on a total surgery time of 3-4 hours), a time-investment we deem justified when taking into account the huge amount of information we are provided with. There are no registered complications in our previous glycocalyx study.

Contacts

Public

Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229HX
NL

Scientific

Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Craniotomy under general anesthesia

- adults between 18 and 70 years of age
- patient diagnosed with cerebral pathology that requires a craniotomy.

Craniotomy awake

- adults between 18 and 70 years
- patient diagnosed with a lesion in an eloquent area of the brain, requiring an awake craniotomy.

Exclusion criteria

child (<18y) or elderly (>70y), pregnancy, diabetes mellitus, familial (combined) hyperlipidemia, smokers or patients with a history of smoking, history of stroke or other cardiovascular diseases, use of cardiovascular medication, silent signs of cerebral small vessel disease on brain MRI or previous cranial surgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	15

Type: Anticipated

Ethics review

Approved WMO

Date: 06-02-2024

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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

CCMO

ID

NL85460.068.23