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Analysis of brain protective effects of different drugs in neurosurgery

Submission date	Recruitment status	[ ] Prospectively registered
15/05/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2024	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/02/2025	Surgery	

Plain English summary of protocol

Background and study aims
Carotid endarterectomy (CEA) is a first-line treatment for preventing stroke in patients with carotid artery stenosis and is effective for both symptomatic and asymptomatic patients. However, the surgery is associated with a relatively high risk (3%) of perioperative cerebral infarction, caused by inadequate cerebral perfusion during temporary carotid artery occlusion. In recent years, optimizing intraoperative strategies for protecting the brain has become a key focus in CEA development. Sevoflurane and propofol are commonly used for maintaining general anesthesia in CEA patients. Propofol is recommended for use in neurosurgical procedures, as studies have demonstrated its brain-protective effects. Propofol can also reduce injury caused by oxidative stress and improve prognosis, although these effects may be limited to mild ischemic injury. Sevoflurane at 1.0-1.5 minimum alveolar concentration (MAC) can protect endothelial cells from ischemia/reperfusion injury, maintain cerebral oxygen supply-demand balance, and reduce the cerebral metabolic rate (CMRO2), thus potentially protecting the brain. Furthermore, near-infrared spectroscopy (NIRS) is superior to other techniques for monitoring regional cerebral oxygen saturation (SrO2) to assess the possibility of cerebral ischemia.

Who can participate?
Randomly selected patients who underwent elective CEA under general anesthesia

What does the study involve?
Participants will be enrolled to compare the levels of brain protection afforded by intravenous anesthesia and combined sevoflurane anesthesia by comparing the changes in SrO2 values during CEA. The objective is to provide a basis for clinical intervention.

What are the possible benefits and risks of participating?
NIRS has the advantages of convenience, rapidity, non-invasiveness, and continuous monitoring. It provides a timely assessment of the supply to cerebral blood vessels, together with damage to the vessels and a dynamic measure of oxygen metabolism in cerebral tissue, and can thus serve as the "first alarm" for cerebral hypoxia and assist anesthesiologists in making effective decisions. The use of combined inhalation anesthesia with sevoflurane and propofol can significantly enhance the role of SrO2, increase the SrO2 on the surgical side of CEA patients

during surgery, alleviate oxidative stress reactions caused by ischemia-reperfusion, improve patient quality of life, and reduce the incidence of postoperative complications.

Risks not provided at time of registration

Where is the study run from?
First Affiliated Hospital of Xinjiang Medical University/Xinjiang Key Laboratory of Perioperative Organ Protection (China)

When is the study starting and how long is it expected to run for?
June 2019 to December 2020

Who is funding the study?
First Affiliated Hospital of Xinjiang Medical University/Xinjiang Key Laboratory of Perioperative Organ Protection (China)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Analysis of the effects of general intravenous anesthesia and combined inhalation anesthesia on regional cerebral oxygen saturation and brain protection during carotid endarterectomy

Study objectives
The use of combined inhalation anesthesia is hypothesized to be more effective compared to intravenous anesthesia in improving strontium peroxide (Sr O2) levels, increasing the SrO2 on the affected side during carotid endarterectomy (CEA), mitigating oxidative stress cause by ischemia-reperfusion injury, improving the overall quality of patient survival post-surgery, and reducing the incidence of postoperative complications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/10/2018, Medical Ethics Committee of The First Affiliated Hospital of Xinjiang Medical University (Department of Anesthesiology, the First Affiliated Hospital of Xinjiang Medical University/Xinjiang Key Laboratory of Perioperative Organ Protection, Urumqi, Xinjiang, 830054, China; None provided; 931701280@qq.com), ref: K201810-01

Study design
Interventional randomized parallel-group single-center study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Reduce the occurrence of postoperative complications in surgical patients

Interventions
Patients undergoing unilateral carotid endarterectomy (CEA) in the hospital will be randomly assigned to two groups, Group A (general intravenous anesthesia) and Group B (combined inhalation anesthesia). Randomisation is performed by adopting the random number table method. All patients will receive the same induction protocol. In Group A, propofol and remifentanil will be used intraoperatively until the end of surgery. In Group B, anesthesia will be maintained using sevoflurane, propofol, and remifentanil. Sevoflurane inhalation will be stopped after the carotid arteries (common, internal, and external carotid arteries) exposure until the end of surgery. Adjustments will be made according to the different stages of the CEA surgery. Hemodynamic parameters will be maintained within ±10% of the baseline values from the start of surgery until carotid artery clamping. When the carotid artery is temporarily clamped to block blood flow, aramine will be pumped intravenously to maintain the hemodynamic parameters within +20% of the baseline values. After carotid artery exposure, hemodynamic parameters will be maintained within 0 to -10% of baseline values. The heart rate (HR), percutaneous cerebral oxygen saturation (SpO2), mean arterial pressure (MAP), and SrO2 will be recorded at different time points, specifically, 5 min before induction of anesthesia (T0), 5 min before carotid artery clamping (T1), immediately after clamping (T2), 5 min after clamping (T3), 10 min after clamping (T4), 15 min after clamping (T5), and 15 min after the restoration of the carotid artery blood flow (T6). Blood samples will be collected at T1, T6, and 24 h after surgery (T7) for arterial blood gas analysis and S100-β protein detection.

Intervention Type
Procedure/Surgery

Primary outcome measure
The heart rate (HR), percutaneous cerebral oxygen saturation (SpO2), mean arterial pressure (MAP), and SrO2 are measured using the recording of data through the monitor and the recording of test results 5 min before induction of anesthesia (T0), 5 min before carotid artery clamping (T1), immediately after clamping (T2), 5 min after clamping (T3), 10 min after clamping (T4), 15 min after clamping (T5), and 15 min after the restoration of the carotid artery blood flow (T6)

Secondary outcome measures
Arterial blood gas analysis and S100-β protein detection measured using the recording of data through the monitor and the recording of test results in blood samples collected at T1, T6, and 24 h after surgery (T7)

Overall study start date
01/06/2019

Completion date
30/12/2020

Eligibility

Key inclusion criteria

1. Patients classified as grade II or III according to the criteria of the American Society of Anesthesiologists (ASA)
2. No restrictions on age or sex
3. Unilateral carotid artery stenosis indicated by transcranial angiography (≥70% stenosis in asymptomatic patients or ≥50% stenosis in symptomatic patients)
4. Capable of autonomous behavior
5. Voluntarily signing an informed consent

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
60

Total final enrolment
54

Key exclusion criteria
1. Acute phase of cerebrovascular disease
2. Carotid artery occlusion
3. Non-visualization of distal carotid artery stenosis
4. Persistent neurological deficits
5. Long-term use of sedatives or antidepressants
6. Systemic consumptive diseases
7. Severe arrhythmias; myocardial infarction, heart failure, or poorly controlled severe hypertension
8. Severe diseases of the respiratory system

Date of first enrolment
01/07/2019

Date of final enrolment
20/12/2020

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Xinjiang Medical University/Xinjiang Key Laboratory of Perioperative Organ Protection

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Sponsor information

Organisation
First Affiliated Hospital of Xinjiang Medical University

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Sponsor type
Hospital/treatment centre

Website
http://en.xydyfy.com/index.php?m=content&c=index&a=show&catid=6&id=13

ROR
https://ror.org/02qx1ae98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First Affiliated Hospital of Xinjiang Medical University/Xinjiang Key Laboratory of Perioperative Organ Protection

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/02/2025	17/02/2025	Yes	No