ISRCTN31527328 https://doi.org/10.1186/ISRCTN31527328

The preventive and therapeutic effects of electroacupuncture on blood pressure and heart rate reduction in carotid artery stenting

Submission date
24/02/2025

Recruitment status
Recruiting

Registration date
05/03/2025

Overall study status
Ongoing

Last Edited
03/03/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Carotid sinus reflex (CSR) is a common complication during and after carotid artery stenting (CAS), clinically manifested as bradycardia (slow heart rate) and hypotension (low blood pressure), which poses significant risks to patient safety. This study aims to investigate the effects of electroacupuncture on carotid sinus reaction occurring during and after carotid artery stenting.

Who can participate?
Patients aged 18-75 years diagnosed with carotid artery stenosis requiring carotid artery stenting

What does the study involve?
Participants will receive electroacupuncture treatment. The treatment is designed to stabilize hemodynamic changes (heart rate and blood pressure) during and after the carotid artery stenting procedure. The study will compare the outcomes of patients who receive electroacupuncture with those who do not, to evaluate its effectiveness in preventing or reducing carotid sinus reaction.

What are the possible benefits and risks of participating?
Possible benefits:
1. Participants may experience improved stabilization of heart rate and blood pressure during and after the procedure.
2. The study may contribute to a better understanding of how electroacupuncture can help manage carotid sinus reflex, potentially benefiting future patients with similar conditions.
Possible risks:
1. Normal reactions during acupuncture: You may experience sensations such as soreness, numbness, heaviness, or swelling, which are normal reactions to acupuncture. Additionally, dizziness may occur due to your physical condition or emotional tension, but it can be alleviated by stopping the acupuncture and resting appropriately.
2. Adverse reactions after acupuncture: Bleeding or hematoma may occur, but these can be

resolved with local pressure. If an infection develops at the acupuncture site, your doctor will address it promptly.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
November 2024 to June 2026

Who is funding the study?
Beijing Hospital of Traditional Chinese Medicine (China)

Who is the main contact?
1. Dr Shaosong Wang, wangssmail@163.com
2. Dr Chuanjin Song, songcjmail@163.com

Contact information

Type(s)
Public, Scientific

Contact name
Ms Chuanjin Song

ORCID ID
https://orcid.org/0009-0001-0976-7676

Contact details
Beijing Hospital of Traditional Chinese Medicine
Beijing
China
100010
+86 (0)17812003007
songcjmail@163.com

Type(s)
Principal investigator

Contact name
Dr Shaosong Wang

Contact details
Beijing Hospital of Traditional Chinese Medicine
Beijing
China
100010
+86 (0)13269211249
wangssmail@163.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Vagal regulation-mediated effects of electroacupuncture on prevention and treatment of carotid sinus reflex in patients undergoing carotid artery stenting

Study objectives
Electroacupuncture can prevent and treat carotid sinus reflex induced by carotid artery stenting

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/01/2025, Beijing Traditional Chinese Medical Hospital Ethics Committee (Beijing Hospital of Traditional Chinese Medicine, No. 23, Art Museum Back Street, Dongcheng District, Beijing, 100010, China; +86 (0)10 8790 6734; website@bjzhongyi.com), ref: 2024BL02-139-01

Study design
Multicenter interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Prevention and treatment of carotid sinus reflex in patients undergoing carotid artery stenting

Interventions
The randomization sequence will be generated by a statistician not involved in the trial using the random number table method. The allocation sequence will be concealed in sequentially numbered, sealed, opaque (non-recoverable) envelopes to ensure sequence confidentiality.

Participants will be randomly allocated (1:1) to either the treatment group or control group. One group will receive a single continuous electroacupuncture treatment during the surgical procedure on the operation day. The other group will receive a single continuous non-acupoint shallow needling on the operation day. The treatment duration will span from the beginning to the end of the surgical procedure. Assessments will be conducted at baseline (pre-intervention), on the operation day, daily from surgery completion to discharge, and at 4 weeks post-discharge.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The incidence of carotid sinus reflex (CSR) incidence, calculated by comparing baseline blood pressure/heart rate with the lowest intraoperative and postoperative values recorded via continuous non-invasive monitoring and ECG during and after surgery

Key secondary outcome(s))
1. Incidence of persistent carotid sinus reflex (CSR), measured using continuous hemodynamic monitoring data and anesthesia records intraoperatively and postoperatively until hospital discharge
2. Vasoactive drug utilization rate and postoperative pharmacological rescue rate: the percentage of patients requiring vasopressors/inotropes measured using anesthesia medication records and postoperative nursing charts during the procedure and postoperatively until discharge
3. Adverse event incidence rate: the frequency of complications (e.g., arrhythmias, stroke) measured using medical records and investigator-reported events from procedure initiation until hospital discharge
4. Neurological deficit measured using the NIH Stroke Scale (NIHSS) score at preoperative baseline (1 day before surgery), 1 hour postoperatively, 24 hours postoperatively, on the day of discharge, and 4 weeks post-discharge
5. Length of hospital stay: days from admission to discharge measured using hospital medical records at the time of discharge

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. European Society for Vascular Surgery (ESVS) 2023-defined carotid stenosis
2. CAS-indicated per Chinese Guidelines 2015
3. Willingness for endovascular intervention
4. Aged 18-75 years inclusive
5. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

75 years

Sex
All

Key exclusion criteria
1. Presence of cardiac pacemaker
2. Documented severe dysfunction in any major organ system (cardiac, pulmonary, hepatic, or renal)
3. Identified coagulation disorders
4. Active skin infection at proposed acupuncture sites
5. Indication for emergency surgical intervention or additional neurointerventional procedures
6. Diagnosed psychiatric conditions or documented non-compliance that may compromise treatment protocol adherence
7. Documented intolerance to electroacupuncture therapy or history of severe adverse reactions
8. Anatomically unsuitable vascular access confirmed by imaging studies

Date of first enrolment
22/01/2025

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine
Capital Medical University
Department of Neurology
No. 23, Art Museum Back Street
Dongcheng District
Beijing
China
100010

Study participating centre
Peking University First Hospital
No. 8 Xishiku Street, Xicheng District
Beijing
China
100034

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Hospital of Traditional Chinese Medicine

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes