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Effect of transcutaneous electrical acupoint stimulation on blood pressure variability in patients with acute ischemic stroke undergoing intravenous thrombolysis

Submission date 24/06/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/06/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/06/2025	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute ischemic stroke (AIS) is the most common type of stroke, and intravenous thrombolysis is currently recognized as the main treatment. AIS patients are prone to increased short-term blood pressure variability in the acute phase, and blood pressure fluctuation has a more direct impact on cerebral perfusion. Reducing blood pressure variability in patients is of great significance for reducing the occurrence of adverse complications such as bleeding and long-term neurological prognosis. It has been reported that acupuncture plays a role in blood pressure regulation. Transcutaneous electrical acupoint stimulation, as a non-invasive alternative to acupuncture, is promising in blood pressure regulation. This study aims to investigate the efficacy of transcutaneous electrical acupoint stimulation (TEAS) in reducing ultra-early blood pressure variability (BPV) in patients undergoing intravenous thrombolysis.

Who can participate?
Adults aged 18 to 80 years undergoing intravenous thrombolysis for acute ischemic stroke.

What does the study involve?
Patients with acute ischemic stroke who were evaluated in the Emergency Department of Beijing Hospital of Traditional Chinese Medicine and the Emergency Department of Peking University First Hospital for treatment with intravenous thrombolysis were invited to join the study. The trial was explained to the participants, and they were asked to provide written informed consent. Participants will be assigned to two groups, each with an equal chance (like flipping a coin). One group will receive transcutaneous electrical acupoint stimulation for approximately 1 hour, from the beginning to the end of intravenous thrombolysis. The other group will receive sham transcutaneous electrical acupoint stimulation for 1 hour using an unplugged electrical stimulation apparatus. Treatment duration is 1 hour with assessments at baseline (before the intervention), 15, 30, 45, 60 and 70 minutes.

What are the possible benefits and risks of participating?
The reduction of blood pressure fluctuation, the reduction of adverse reactions and the reduction of neurological impairment during intravenous thrombolysis may be the possible benefits of AIS patients participating in this study. The control group did not guarantee improvement in blood pressure variability in patients. The control group was still treated with conventional symptomatic Western medicine. The information gained from this study may benefit future patients with the same disease.

Adverse reactions may occur after transcutaneous electrical acupoint stimulation, but they are few and mild. Local muscle spasms may occur during electrical stimulation because of the patient's physical problems or emotional stress, which can be relieved after stopping the electrical stimulation and proper rest. However, if skin burns, pain, etc., occur at the site of TEAS, the patient will receive immediate medical attention, and the research team will reevaluate whether they can continue the treatment.

Where is the study run from?
1. Beijing Traditional Chinese Medicine Hospital acupuncture department (China)
2. Peking University First Hospital (China)

When is the study starting and how long is it expected to run for?
March 2025 to January 2026

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

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
A clinical randomized controlled study of transcutaneous electrical acupoint stimulation for blood pressure variability in intravenous thrombolysis for stroke

Study objectives
A clinical randomized controlled study of transcutaneous electrical acupoint stimulation for blood pressure variability in intravenous thrombolysis for stroke

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/03/2025, Beijing Traditional Chinese Medical Hospital Ethics Committee (Beijing Traditional Chinese Medicine Hospital, No. 23, Art Museum Back Street, Dongcheng District, Beijing, 100010, China; +82 010 8970 6734; website@bjzhongyi.com), ref: 2025BL02-006-02

Primary study design
Interventional

Study design
Multicenter interventional randomized single-blinded parallel-group controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ultra-early blood pressure variability in patients with acute ischemic stroke treated with intravenous thrombolysis

Interventions
Participants will be randomly allocated (1:1) to either the treatment or the control group. One group will receive transcutaneous electrical acupoint stimulation for approximately 1 hour, from the beginning to the end of intravenous thrombolysis. The other group will receive sham transcutaneous electrical acupoint stimulation for 1 hour using unplugged electrical stimulation apparatus. Treatment duration is 1 hour with assessments at baseline (before the intervention), 15, 30, 45, 60 and 70 minutes.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Blood pressure values measured using a mercury sphygmomanometer at baseline, 15, 30, 45, and 60 min after the start of thrombolysis, and 10 min after the completion of thrombolysis
2. Calculated blood pressure variability values measured using data collected during the above 7 blood pressure values monitoring at baseline, 15, 30, 45, and 60 min after the start of thrombolysis, and 10 min after the completion of thrombolysis

Key secondary outcome(s)
1. The level of alertness and agitated behavior in patients measured using the Richmond Agitation-Sedation Scale (RASS) at baseline, 30 and 60 min
2. The severity of a stroke measured using the National Institutes of Health Stroke Scale (NIHSS) at baseline, 30 and 60 min
3. The occurrence of adverse events (during thrombolysis: fluctuation of symptoms, aggravation of disease, forced cessation of thrombolysis, various bleeding, application of antihypertensive drugs, application of sedative drugs; after thrombolysis: ischemia aggravation, cerebral hemorrhage, rescue use of antihypertensive drugs, etc.) measured using data observed and recorded during the process of intravenous thrombolysis at any time

Completion date
29/03/2026

Eligibility

Key inclusion criteria
1. No gender limit
2. Age ≥18 years old
3. Meet the diagnostic criteria of acute ischemic stroke
4. Consistent with the indications of intravenous thrombolysis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Coagulopathy, severe liver and kidney dysfunction
2. Implantation of metal or electronic implantable devices such as a cardiac pacemaker
3. History of epilepsy
4. Being pregnant or breastfeeding, or intending to become pregnant within the next 6 months
5. Damage, inflammation, scar, etc. on the skin of the acupoints; Sensory disturbance or allergy to electrical stimulation)
6. Patients could not tolerate transcutaneous electrical stimulation

Date of first enrolment
30/03/2025

Date of final enrolment
20/01/2026

Locations

Countries of recruitment
China

Study participating centre

Beijing Traditional Chinese Medicine Hospital
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Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Traditional Chinese Medicine Hospital

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
Published as a supplement to the results publication