

Is electroacupuncture better than sham electroacupuncture for ischemic stroke? What is the mechanism of it?

Submission date 13/04/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/04/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/05/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Stroke is the second leading cause of disability and death across the world. The annual number of strokes and deaths caused by stroke increased constantly, and the stroke burden has been increasing in recent years. Ischemic stroke composed 62.4% of total incident strokes in 2019. Mechanical thrombectomy (removing a blood clot through a catheter) and intravenous thrombolysis (injection of clot-busting drugs) are recommended for acute ischemic stroke but strict period windows and indications limit their clinical use. The aim of this study is to evaluate the effectiveness and reveal the mechanism of electroacupuncture (EA) for ischemic stroke.

Who can participate?

Patients aged 18-80 years with acute and subacute ischemic stroke

What does the study involve?

Patients will be randomly allocated to two groups. The patients in the EA group will receive EA treatment, while the sham EA group will receive sham EA. Participants will be evaluated at the start of the study, 24 hours after the first treatment, and at weeks 1, 2 and 3 and blood samples will be collected.

What are the possible benefits and risks of participating?

Both groups will receive basic treatment and symptomatic treatment. Participants' symptoms may be relieved in this study. Acupuncture may cause some slight side effects, including bleeding, hematoma, serious pain, and dizziness. These side effects are generally mild and rarely cause serious harm.

Where is the study run from?

Luohu District Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?

November 2022 to October 2025

Who is funding the study?
Science, Technology and Innovation Commission of Shenzhen Municipality (China)

Who is the main contact?
Prof. Hong Zhao, hongzhao2005@aliyun.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Efficacy and mechanism of electroacupuncture in the treatment of ischemic stroke: a prospective randomized controlled trial

Study objectives
Electroacupuncture (EA) has better efficacy than sham EA in improving neurological function. EA improved neurological function by regulating serum RNA and metabolites.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 07/02/2023, Ethics Committee, Luohu District Hospital of Traditional Chinese Medicine (16 Xiantong Rd. Luohu District, Shenzhen, 518004, China; +86 (0)755 82311699; lhzyykjk@163.com), ref: 2023-LHQZYYYXLL-KY-001

Study design

Single-center two-armed single-blind prospective randomized controlled interventional trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute and subacute ischemic stroke patients

Interventions

Eligible patients will be randomly allocated into the EA group or sham EA group. SPSS 26.0 will be used to generate the randomization sequence and allocation ratio. Group allocation data will be concealed in predetermined, sequentially numbered, opaque, and sealed envelopes, produced by a third-party professional statistician.

The EA group will receive EA while the sham EA group will receive sham EA. Acupoints in both groups are as follows: Baihui (GV20), affected side Zusanli (ST36), affected side Futu (ST32), affected side Shousanli (LI10), affected side Shouwuli (LI13). The participants will receive EA or sham EA treatment 30 times in 3 weeks, five times a week.

Disposable single-use sterile needles will be inserted into acupoints at a depth of 5–15 mm after the skin is disinfected with alcohol. The HANS EA apparatus will be connected to needles. Electric stimulation will be operated with a dense-disperse wave, 20 Hz/100 Hz in frequency. The current intensity will be 5-10 mA in the acute phase while 1-3 mA in the subacute phase. Each treatment will last for 30 min. The sham EA group will receive sham EA, which uses a blunt needle without skin current.

Intervention Type

Other

Primary outcome(s)

Neurological dysfunction assessed using the National Institute of Health stroke scale (NIHSS) at baseline, 24 hours after the first treatment, and weeks 1, 2 and 3

Key secondary outcome(s)

1. Neurological function measured using the Fugl-Meyer Assessment (FMA) at baseline and weeks 1, 2 and 3
2. Activity of daily living measured using the Modified Barthel index (MBI) at baseline and weeks 1, 2 and 3
3. Cognitive function measured using the Mini-Mental State Examination (MMSE) at baseline and weeks 1, 2 and 3
4. Transcriptomic sequencing using blood samples collected before the first treatment, 24 hours after the first treatment, and weeks 1, 2 and 3

5. Metabolomic sequencing using blood samples collected before the first treatment, 24 hours after the first treatment, and weeks 1, 2 and 3

Completion date

31/10/2025

Eligibility

Key inclusion criteria

1. A diagnosis of ischemic stroke according to the American Heart Association/American Stroke Association
2. Participants with acute and subacute stroke, the stroke onset within 2 weeks
3. Aged 18 to 80 years old
4. After treatment, symptoms were stable
5. Patients are conscious and are able to finish all examinations and evaluations
6. Patients sign a written informed consent and voluntarily participate in this study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with severe heart, lung, liver, and kidney dysfunction
2. Patients with diseases which affect cognitive function assessment, including neurodegenerative diseases, mental illnesses, and others
3. Patients with diseases which affect motor function assessment, including epilepsy, movement disorders, and others
4. Patients with aphasia, severe visual and auditory disorders
5. Patients with brain tumor and craniocerebral injury
6. Long-term using sedatives and antidepressants
7. Patients cannot receive electroacupuncture treatment, due to needle fainting, and cannot cooperate with the researcher for other reasons

Date of first enrolment

15/02/2023

Date of final enrolment

01/10/2025

Locations

Countries of recruitment

China

Study participating centre

Luohu District Hospital of Traditional Chinese Medicine

16 Xiantong Road Luohu District

Shenzhen

China

518004

Sponsor information

Organisation

Science, Technology and Innovation Commission of Shenzhen Municipality

Funder(s)

Funder type

Government

Funder Name

Science, Technology and Innovation Commission of Shenzhen Municipality

Alternative Name(s)

Shenzhen Science and Technology Innovation Commission, Shenzhen Science and Technology Innovation Committee,

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

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