ISRCTN98312560 https://doi.org/10.1186/ISRCTN98312560

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

Submission date
13/04/2023

Recruitment status
Recruiting

Registration date
15/04/2023

Overall study status
Ongoing

Last Edited
26/05/2023

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Contact name
Prof Hong Zhao

ORCID ID
http://orcid.org/0000-0001-8211-9483

Contact details
16 Xiantong Rd
Luohu District
Shenzhen
China
518004
+86 (0)755 25160866
hongzhao2005@aliyun.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure

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

Secondary outcome measures
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

Overall study start date
02/11/2022

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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

Sponsor details
Zone C, Civic Center
Fuzhong 3rd Road
Futian District
Shenzhen
China
518035
+86 (0)0755 82001112
complain@sticmail.sz.gov.cn

Sponsor type
Government

Website

http://stic.sz.gov.cn/

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

Publication and dissemination plan
The researchers intend to publish the protocol before December 2023. They plan to publish results in October 2025.

Intention to publish date
01/04/2026

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