ISRCTN99117074 https://doi.org/10.1186/ISRCTN99117074

Effect of acupuncture therapy on cerebrovascular capacity in acute stroke patients

Submission date 04/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 20/04/2016	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 27/06/2017	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off. Around 80% of strokes are ischemic strokes, in which the arteries that supply the brain with oxygen become narrowed or blocked, causing severely reduced blood flow (ischemia). As we age, a gradual build-up of a sticky substance called plaque can build-up in these arteries. An acute cerebral infarction is a type of ischemic stroke in which these arteries become blocked suddenly by a blood clot, reducing blood flow to the brain (cerebral perfusion) and starving it of oxygen. It has been found that a type of acupuncture called waking up spirit needling can help to improve symptoms in stroke patients. Acupuncture is widely used in stroke treatment, but the way that it works is still unclear. The aim of this study is to find out whether the waking up spirit needling method of acupuncture can help to improve blood flow to the brain and relieve symptoms in stroke patients.

Who can participate?
Adults who have had a acute cerebral infarction and are experiencing reduced by flow to the brain.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive acupuncture with waking up spirit needling method. Participants in the second group receive twelve hand and foot acupuncture. For all participants, acupuncture sessions take place every day on weekdays, with a break over the weekend, for two weeks and last for around 35 minutes per session. Participants undergo a breathing test while having the blood supply to their brain measured using an ultrasound probe (device which uses sound waves to view the blood vessels that supply the brain) at the start of the study and then again after one and two weeks of treatment. Participants also complete a number of questionnaires in order to find out if their has been any change to their nerve function or ability to complete daily activities.

What are the possible benefits and risks of participating?
It is expected that participants will benefit from relief of pain as well as improved function and

strength. There is a small risk that the acupuncture treatment could make participants feel nauseous, faint or experience a temporary increase in pain either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

When is the study starting and how long is it expected to run for?
April 2016 to May 2017

Who is funding the study?
The Beijing Municipal Administration of Traditional Chinese Medicine (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Clinical study to assess the influence of acupuncture with waking up spirit needling method on cerebrovascular reserve capacity of patients with acute cerebral infarction

Study objectives
Acupuncture with waking up spirit needling method can improve the cerebral vascular reserve (CVR) capacity of patients with acute cerebral infarction, thus reducing the scores of National Institutes of Health Stroke Scale (NIHSS) and preventing the further progression of the disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 30/10/2015, ref: 20151130

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Acute cerebral infarction

Interventions
Participants are randomly allocated to one of two groups.

Treatment group: Participants receive acupuncture with waking up spirit needling method
1. Acupuncture bloodletting will be conducted at acupoints Baihui (DU20), Sishencong (EX-HN1) or twelve well points, the needle will be withdrawn immediately, and skin around the pin holes be squeezed to exanguinate a few drops of blood.
2. Other points like Renzhong (GV 26), Chengjiang (CV 24), Fengchi (GB 20), Hegu (LI 4), Laogong (PC 8), Taichong (LV 3), and Yongquan (KI 1)will be chosen after the bloodletting to take acupuncture, the needles will be retained for 30 minutes.

Control group: Participants receive twelve hand and foot acupuncture. This involves the acupoints including Quchi (LI 11), Neiguan (PC 6), Hegu (LI 4), Yanglingquan (GB 34), Zusanli (ST 36), and Sanyinjiao (SP 6),which will be chosen to take acupuncture, the needles will be retained for 30 minutes.

Participants in both groups receive treatment once a day on weekdays, with a break at the weekend, for a total of two weeks. Each treatment session lasts approximately 35 minutes, with 5 minutes to place the needles and 30 minutes for the needles to remain in place before removal.

All participants are followed up at 1 and 2 weeks post randomisation.

Intervention Type
Other

Primary outcome measure
1. Cerebral vascular reserve (CVR) capacity is determined using the mean blood flow velocity (MFV) of the middle cerebral arteries, as measured with Transcranial Doppler (TCD) breath holding test at baseline and 2 weeks
2. Breath-holding index (BHI) is measured at baseline and 2 weeks

CVR detection method: Transcranial doppler breath holding test is applied. Patients are instructed how to hold the breath, and then they practice for twice before the detection. Patients take supine position, breath peacefully for 5 minutes. Then two ultrasonic probes of TCD machine (EMS-9W, Nanjing Bang'ao Medical Apparatus Ltd. Co., Nanjing, China) are put on bilateral temporal windows with depth of 50-55 mm to measure the blood velocity of bilateral middle cerebral artery, M1. When the best blood flow signal is obtained, the probes are fixed. The mean blood flow velocity is recorded as patients in a calm state. Then patients are asked to hold breath for at least 15 seconds, and the mean blood flow velocity is recorded again.
CVR = (After holding breath MFV - Before holding breath MFV)/ Before holding breath MFV×100%. CVR function is impaired if CVR is less than 20%.
BHI = (After holding breath MFV- Before holding breath MFV) / Before holding breath MFV×(100 /time holding breath).

Secondary outcome measures
1. Nerve function is measured using the national institutes of health stroke scale (NIHSS) at baseline, 1 week and 2 weeks
2. Performance in activities of daily living is measured using the Barthel Index at baseline, 1 week and 2 weeks

Overall study start date
01/04/2016

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Aged between 30 to 80 years old with acute cerebral infarction, and their onset time is less than 7 days
2. Meet the western medicine diagnostic criterion for cerebral infarction issued by American Heart Association/American Stroke Association, AHA/ASA in 2013
3. Meet the traditional Chinese medicine diagnostic criterion developed according to the Stroke Diagnosis and Curative Effect Evaluation Standard (Draft) by State Administration of Traditional Chinese Medicine, Acute Encephalopathy Research Group
4. Diagnosis confirmed by head CT or MRI

5. Confirmed with CVR impairment by breath-holding test
6. With NIHSS score larger than or equal to 5 points, or less than or equal to 20 points, and Glasgow Coma Scale score larger than or equal to 12 points
7. Agree to participant in this trial and assign the informed consent.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Using antithrombotics such as Low Molecular Heparin because of some other disease
2. Carotid artery stenting
3. Serious heart, lung or kidney diseases
4. Do not coordinate the brain ultrasound examination or quantitative score evaluation due to other diseases

Date of first enrolment
30/04/2016

Date of final enrolment
20/05/2017

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to the Capital Medical University
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Sponsor information

Organisation

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/013xs5b60

Funder(s)

Funder type
Government

Funder Name
The Beijing Municipal Administration of Traditional Chinese Medicine

Results and Publications

Publication and dissemination plan
1. Planned publication of study protocol in BMJ Open
2. Planned publication of results paper in BMJ Open
3. Planned publication of 1-2 papers about acupuncture and cerebral vascular capacity in Chinese Core Journals

Intention to publish date
15/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/06/2017		Yes	No