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Acupuncture-induced changes on brain excitability for stroke patients with motor dysfunction

Submission date
04/09/2016

Recruitment status
No longer recruiting

Registration date
18/10/2016

Overall study status
Completed

Last Edited
18/10/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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). This can lead to serious complications, depending on which part of the brain is deprived of oxygen and for how long. One of the most common long-term complications from stroke is weakness on one side of the body (hemiparesis). Acupuncture is a popular treatment taken from ancient Chinese medicine, in which fine needels are placed into the body at specific points. Studies have shown that it can lead to an improvement in hemiparesis following stroke, however the exact mechanism for this is not known, in particular, whether it affects the movement centre of the brain. The aim of this study is to find out whether acupuncture is able to improve hemiparesis following stroke by affecting the movement centre of the brain.

Who can participate?
Adults who have had a stroke and are experiencing weakness in one hand.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive 40 acupuncture sessions over a period of 12 weeks as well as standard care. Those in second group undergo conventional physical therapy for stroke rehabilitation, involving exercises designed to help recover movement. At the start of the study and then after three months, participants in both groups have a brain scan to find out if the therapy they have had has led to changes in the movement centre of the brain. At the same time, participant's hand function is assessed to find out if it has improved.

What are the possible benefits and risks of participating?
Participants may benefit from recovering movement lost following their stroke. The risks of receiving acupuncture or rehabilitation treatment described in this study are small. In few cases, acupuncture may cause discomfort or pain at the sites during needle insertion, and nausea or feeling faint after insertion. Rehabilitation may lead to muscle sprain, bruising or tiredness.

Where is the study run from?
1. Beijing Hospital of Traditional Chinese Medicine (China)
2. China Rehabilitation Research Center (China)

When is the study starting and how long is it expected to run for?
December 2015 to June 2017

Who is funding the study?
Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding (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
ZYLX201412

Study information

Scientific Title
Characterizing the neurophysiological mechanisms of acupuncture on motor functional recovery after stroke: a randomized controlled study

Study objectives
Acupuncture exerts its positive effects on post-stroke motor behavior by influencing cortical plasticity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine, 24/03/2016, ref: 2016BL-018-01

Study design
Two-arm single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Motor dysfunction after stroke

Interventions
Participants who meet the eligibility criteria will be randomly assigned to one of the two groups in a 1:1 ratio. Randomization will be conducted using computer-generated random numbers placed in sequentially numbered, sealed opaque envelopes and kept by a clinician with no contact to study participants.

Both acupuncture and rehabilitation groups will receive a total of 40 treatment sessions in 12 weeks. Participants in both groups will receive standard medical care for stroke throughout the trial, which will be conducted in accordance with the China Guideline for the Diagnosis and Treatment of Acute Ischemic Stroke (2010).

The acupuncture group will additionally receive manual acupuncture for 12 weeks. Twelve acupoints will be used for all the patients. Each session will last for 40 minutes.

For the control group, patients will undergo conventional physical therapy. The structure of the intervention will be customized to each individual’s functional level. Each session will have a duration of 40 minutes.

Participants in both groups are followed up at the end of the intervention period (12 weeks), at which time they will undergo transcranial magnetic stimulation and motor function testing.

Intervention Type
Supplement

Primary outcome measure
Excitability of primary motor cortex measured by recruitment curve of Motor Evoked Potential by transcranial magnetic stimulation at baseline and 3 months

Secondary outcome measures
1. Motor function of hand and arm are measured using the Action Research Arm Test and the upper-extremity portion of the Fugl-Meyer motor assessment at baseline and 3 months
2. General motor disability is measured using the modified Rankin scale at baseline and 3 months
3. Neurological deficit is measured using National Institutes of Health Stroke Scale assessment at baseline and 3 months
4. The muscle strength level is measured using the UK Medical Research Council standard at baseline and 3 months

Overall study start date
01/12/2015

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. First-ever mono-hemispheric ischemic stroke
2. Within 14 days after stroke onset
3. Hand weakness with MRC level of 1 to 4
4. Aged between 18 and 80

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Participation in other medical studies at present or during the previous 3 months
2. Pre-existing conditions of body dysfunction before stroke attack
3. Pregnancy

4. Cognitive or communication impairment or pre-existing conditions precluding informed consent or compliance with study assessments

Date of first enrolment
01/09/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine
Meishuguanhoujie No. 23
Dongcheng Province
Beijing
China
100010

Study participating centre
China Rehabilitation Research Center
Jiaomenbeilu no.10
Fengtai province
Beijing
China
100068

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine

Sponsor details
Meishuguanhoujie no. 23
Dongcheng District
Beijing
China
100010

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding

Results and Publications

Publication and dissemination plan
The results of this study is about to be presented in an original study paper and published in the second half of 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request