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The efficacy of acupuncture in spasm after stroke

Submission date	Recruitment status	[ ] Prospectively registered
24/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/08/2016	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims.
Spasms are a sudden involuntary contraction of a muscle or a group of muscles. They are a common complication after a stroke. The aim of this study is to test whether acupuncture reduces the rate and severity of spasms after a stroke.

Who can participate?
Patients aged 40-75 who have had a stroke within the last 14 days

What does the study involve?
Participants are randomly allocated into two different groups. The treatment group receive acupuncture treatment and the basic treatment of western medicine for 4 weeks, while the control group receive sham acupuncture and the basic treatment of western medicine for 4 weeks. Both groups are assessed at the start of the study and at 2 weeks, 4 weeks and 12 weeks follow-up.

What are the possible benefits and risks of participating?
The possible benefits of acupuncture include reducing the rate and severity of spasms. Possible risks of acupuncture may include bleeding and bruising.

Where is the study run from?
1. Beijing Traditional Chinese Medical Hospital affiliated with Capital Medical University (China)
2. Beijing Huguosi Chinese Medicine Hospital affiliated with Capital Medical University (China)

When is the study starting and how long is it expected to run for?
August 2009 to December 2013

Who is funding the study?
1. Beijing Municipal Science and Technology Commission (China)
2. Beijing Hospital 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
D09050703550902

Study information

Scientific Title
Comparison of the effect of acupuncture versus sham acupuncture in reducing the incidence rate of spasm and alleviate the severity of spasm in adult patients: a multicentre randomised controlled trial

Acronym
EASS

Study objectives
Spasm is a common neopathy after stroke. Spasticity may influence the recovery of motor function which reduces the patients' quality of life. Experts are now arguing on the efficacy of acupuncture in spasm after stroke. Our study is to verify whether stimulating Jiajixue before the spasm occurs in the acute stage may reduce the incidence rate of spasm and alleviate the severity of spasm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine, 22/01/2010, ref: 201002-1

Study design
Multicentre randomised single-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please contact shizheng83@hotmail.com to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
A total of 254 patients in the acute stage of Cerebral apoplexy will be recruited. One half of the patients are from the Acupuncture Department of Beijing Huguosi Chinese Medicine Hospital while the other half are from the Acupuncture Department of Beijing Hospital of Traditional Chinese Medicine. The patients were randomly divided into two different groups. The treatment group receive the Wang Jiajixue remedy, the standard therapy of acupuncture and the basic treatment of western medicine for 4 weeks, the control group receive the sham acupuncture and the standard therapy of the acupuncture and the basic treatment of western medicine for 4 weeks. Both groups were evaluated at the baseline, 2 weeks, 4 weeks and 12 weeks.

1. The treatment group
1.1. Wang Jiajixue are selected from Jiaji (EX-B2).
Location: 0.3 cun lateral to the lower border of the 2nd, 4th, 6th, 8th, 10th, 12th thoracic vertibra, and the 2nd, 4th lumber vertibra. 8 points on each side.
Methods: lateral lying position, affected limb upwards. Use the uniform reinforcing-reducing method with stainless steel needles of 0.32 mm diameter, 40mm length, perpendicular insertion, the filiform needles are left for 30 minutes after the needling sensation, five days a week. The depth of the insertion is 25mm.

1.2. Standard acupuncture treatment: Quchi (LI-11), Waiguan, Hegu (LI-4), Zusanli (ST-36), Yanglingquan (GB-34), Sanyinjiao (SP-6) on the affected limb. Use the uniform reinforcing-

reducing method with stainless steel needles of 0.32 mm diameter, 40mm length, perpendicular insertion, the filiform needles are left for 30 minutes after the needling sensation, five days a week. The depth of the insertion is 25mm.

1.3. Received standard care; ICP (Intracranial Pressure) control, blood pressure control, platelet aggregation, trophic nerve, routine physiotherapy and occupational therapy for 4 weeks.

2. The control group: the sham acupuncture
2.1. Location: 0.1 cun lateral to the lower border of the 2nd, 4th, 6th, 8th, 10th, 12th thoracic vertibra, and the 2nd, 4th lumber vertibra. 8 points on each side.
Methods: lateral lying position, affected limb upwards. Use the needle of stainless steel needles of 0.32 mm diameter, 40mm length, perpendicular insertion, the filiform needles are left for 30 minutes, no needling sensation, five days a week. The depth of the insertion is 5mm.
Standard acupuncture treatment: Quchi (LI-11), Waiguan, Hegu (LI-4), Zusanli (ST-36), Yanglingquan (GB-34), Sanyinjiao (SP-6) on the affected limb. Use the uniform reinforcing-reducing method with the needle of stainless steel needles of 0.32 mm diameter, 40mm length, perpendicular insertion, the filiform needles are left for 30 minutes after the needling sensation, five days a week. The depth of the needles is 25mm.

2.2. As well as the western medicine standard care for 4 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Modified Ashworth Scale for Spasticity (MASS)
2. Fugl-Meyer (FMA)
3. Motor assessment scale (MAS)
Assessments will be conducted at baseline and at week 2, 4 and 12 follow-up.

Secondary outcome measures
1. Activities of daily living (ADL)
2. The NIH Stroke Scale (NIHSS)
3. Stroke Speciality-Quality of Life (SS-QOL)
4. Modified Rankin Scale (mRS)
Assessments will be conducted at baseline and at week 2, 4 and 12 follow-up, it is likely to adopt the follow up face to face.

Overall study start date
01/08/2009

Completion date
30/12/2013

Eligibility

Key inclusion criteria

1. Stroke patients were diagnosed according to criteria of cerebral arterial thrombosis in Western medicine and the criteria of apoplexy in Chinese medicine
2. Stroke occurred within 14 days
3. Male or female, aged 40-75
4. National Institute of Health Stroke Scale (NIHSS) grade from 4 to 21
5. The muscle strength of the affected limbs is less than grade 3
6. No disorder of consciousness according to Glasgow Coma Scale (GCS)
7. Patients suffering their first attack or with a cerebral stroke history but with on serious deformity, modified Rankin SCale (mRS) grade >1
8. Diagnosed by the computed tomography (CT) or magnetic resonance imaging (MRI)
9. Patients who took part in the trial voluntarily and signed the informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
254

Key exclusion criteria
1. Patients receiving treatment for thrombolysis
2. Patients also have other neurological diseases or other illness which may cause abnormal muscle tension
3. Patients involved in other clinical trials, or having undergone other clinical trials in the last 3 months
4. Patients with severe primary diseases of the cardiovascular system, liver, kidney, hematopoietic system, or psychopathy
5. Pregnant women or women who are breastfeeding
6. Congenital disabilities

Date of first enrolment
01/08/2009

Date of final enrolment
30/12/2013

Locations

Countries of recruitment
China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine
Beijing
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Sponsor type
Hospital/treatment centre

Website
www.bjzhongyi.com

Organisation
Beijing Municipal Science & Technology Commision

Sponsor details

Sponsor type
Government

Website
http://www.bjkw.gov.cn/n244495/

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Municipal Science and Technology Commission (China)

Funder Name
Beijing Hospital of Traditional Chinese Medicine (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration