

# The Efficacy of Acupuncture in Stroke Recovery

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<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/05/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Lingpeng Wang

### Contact details

Beijing Hospital of Traditional Chinese Medicine  
No.23 Meishuguanhoujie  
Dongcheng Dis.  
Beijing  
China  
100010  
+86 (0)10 5217 6636  
wlp5558@sina.com

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

D08050703550902

## Study information

**Scientific Title**

The effect of acupuncture versus standard Western therapy in reducing the rate of deformity of stroke and in improving the quality of life in adult patients: a multicentre randomised controlled trial

**Acronym**

EASR

**Study objectives**

Under the guidance of the theory of Chinese medicine, acupuncture is widely used in treating the stroke in China for a long time. This study is to evaluate the effect of acupuncture in reducing the rate of deformity of stroke and in improving the quality of life.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Research Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine approved on the 22nd January 2010 (ref: 201002-1)

**Study design**

Multicentre randomised controlled study

**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 contact shizheng83@hotmail.com to request a patient information sheet

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

Stroke

**Interventions**

A total of 328 patients on the acute stage of cerebral apoplexy will be recruited. The patients were randomly divided into two different groups: the intervention group received the treatment of acupuncture and the Western Medicine standard treatment for 3 months and the secondary prevention treatment for 6 months, and the control group received the standard therapy of the Western medicine for 3 months and the secondary prevention treatment for 6 months. Both groups were evaluated with the treatment course of 4 weeks, 12 weeks and 24 weeks.

#### Group A (intervention group):

Patients are stimulated by 7 main acupoints: Baihui (Du-20), Quchi (LI-11), Shousanli (LI-10), Hegu (LI-4), Zusanli (ST-36), Yanglingquan (GB-34), Sanyinjiao (SP-6). Acupoints association is used under the guidance of the theory of Chinese medicine and according to the patients' different symptoms, the acupoints below are commonly used: Jianyu (LI-15), Huantiao (GB-10), Qixu (GB40), twelve well-jing points, Jinjin (EX-HN 12), Yuye (EX-HN 13), Yamen (DU-15), Lianquan (RN 23), Tianshu (ST-25), Fenglong (ST-40), limb spasm assists with fire needles.

The acupoints are stimulated by the filiform needles and the needles are remained for 30 minutes. Patients on the acute stage are treated with the acupoints of Baihui (Du-20), Jinjin (EX-HN 12), Yuye (EX-HN 13), Sishencong (EX-HN 1) and the twelve well-jing points, that use quick insertion of the tri-ensiform needles for bleeding. The needles are remained for 30 minutes every other day, three times a week.

As well as the western medicine standard therapy for 3 months and the secondary prevention treatment (the blood pressure control, platelet aggregation, glucose control, etc) for 6 months.

#### Group B:

Received the treatment of the standard therapy - the intracranial pressure (ICP) control, the blood pressure control, platelet aggregation, routine physiotherapy and occupational therapy, the secondary prevention treatment as well.

#### Joint Sponsor:

Beijing Hospital of Traditional Chinese Medicine (China)

No. 23 Meishuguanhoujie

Dongcheng District

Beijing 100010

China

T: +86 (0)10 5217 6852

F: +86 (0)10 5217 6808

Email: [postmaster@bjzhongyi.com](mailto:postmaster@bjzhongyi.com)

Website: <http://www.bjzhongyi.com>

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

1. Barthel Index (BI)
2. Stroke-Specific Quality Of Life (SS-QOL)

Assessments will be conducted at the baseline and at week 4, 12 and 24 follow-up.

#### Secondary outcome measures

1. The National Institutes of Health Stroke Scale (NIHSS)
2. Modified Rankin Scale (mRS)

Assessments will be conducted at the baseline and at week 4, 12 and 24 follow-up.

**Overall study start date**

01/09/2009

**Completion date**

30/06/2012

## 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. The stroke patients were hospitalised because of the acute cerebral arterial thrombosis, that occurred in 10 days
3. Male or female, aged 40 - 75 years
4. National Institutes of Health Stroke Scale (NIHSS) grade from 4 to 21
5. Glasgox Coma Score greater than or equal to 7
6. Patients on the first attack or with a cerebral stroke history but with on serious deformity, modified Rankin Scale (mRS) grade less than or equal to 1
7. Patients who took part in the trail voluntarily and signed the informed consent form

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

328

**Key exclusion criteria**

1. Patients under the treatment of thrombolysis
2. Patients under other clinical trials, or having undergone other clinical trials in the last 3 months
3. Patients with severe primary diseases in cardiovascular system, liver, kidney, hematopoietic system, and psychopathy
4. Pregnant women or women in breast feeding period
5. Inborn handicaps

**Date of first enrolment**

01/09/2009

**Date of final enrolment**

30/06/2012

## Locations

**Countries of recruitment**

China

**Study participating centre**  
**Beijing Hospital of Traditional Chinese Medicine**  
Beijing  
China  
100010

## **Sponsor information**

**Organisation**  
Beijing Municipal Science and Technology Commission (China)

**Sponsor details**  
No. 16 Xizhimendajie  
Xicheng Dis.  
Beijing  
China  
100035  
+86 (0)10 6615 3395  
bjkwwz@sina.com

**Sponsor type**  
Government

**Website**  
<http://www.bjkw.gov.cn/n1143/index.html>

**ROR**  
<https://ror.org/034k14f91>

## **Funder(s)**

**Funder type**  
Government

**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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	12/11/2012		Yes	No