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The Efficacy of Acupuncture in Stroke Recovery

Submission date 11/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 29/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/05/2013	**Condition category** Circulatory System	[_] Individual participant data [_] 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), Qiuxu (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
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?
Protocol article	protocol	12/11/2012		Yes	No