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The Efficacy of Acupuncture and Moxibustion in Urination Disorders 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
19/10/2010	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
D08050703550902

Study information

Scientific Title

The effect of both acupuncture and moxibustion versus standard Western therapy in reducing the rate of deformity of stroke and in improving the symptoms of urination disorders after stroke in adult patients: a multicentre randomised controlled trial

Acronym
EAMUDS

Study objectives
Stroke can lead to the urination disorders, for instance, urinary incontinence, urgency of urination and urinary frequency. Urination disorders may severely influence the patients' quality of life and contribute to the burden of medical care. This study is to explore the acupuncture and moxibustion in improving the symptoms of urination disorders after stroke and the quality of the patients' lives.

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)

Primary study design
Interventional

Study design
Multicentre randomised single blind controlled study

Study type(s)
Treatment

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

Interventions
A total of 120 patients in the recovery stage of cerebral apoplexy will be recruited. All of the 120 patients are from the Acupuncture Department of Beijing Huguosi Chinese Medicine Hospital and the Acupuncture Department of Beijing Hospital of Traditional Chinese Medicine. 60 patients fit the description for the syndrome of deficiency of kidney-yang and 60 patients fit the description for the syndrome of deficiency of qi.

1. The patients with the syndrome of deficiency of kidney-yang were randomly divided into two different groups with the ratio of 2:1.
1.1.The experimental group (A) received the acupuncture and moxibustion remedy for 4 weeks: Cut the fresh ginger into slices (thickness 6-7mm, diameter 40-50mm), pierce several holes on the ginger. Put the mugwort floss (height 30mm, diameter 30mm, column) on the slices of gingers. Fill the salt in Shenque (RN-8) and place the slice of ginger on Shenque, light the mugwort floss, until it burnout, for 3 zhuangs, once a day, five days a week.
1.2. The patients of the controlled group (B) wait for 4 weeks with no therapy.

2. The patients with the syndrome of deficiency of qi were randomly divided into two different groups with a ratio of 2:1.
2.1. The experimental group (C) received the electro acupuncture remedy for 4 weeks: Needling Ciliao (BL-31) and Huiyang (BL-35), on both sides of the body. Oblique insertion into the 2nd posterior sacral foramina to depth of 80mm, with electrified needling sensation to external genitalia. Perpendicular needling in Huiyang, if a sore and distended needling response then lift the needles a little, link up the electric impulse acupuncture units, choose frequency 50 hz. Gently adjust the frequency as much as the patients can endure, apply the needles for 30 minutes, once a day, five days a week.
2.2. The patients of the controlled group (D) wait for 4 weeks with no therapy.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The number of incontinence and normal micturition episodes in 72 hours. Assessed by a micturition diary over 4 weeks.

Key secondary outcome(s)
1. Questionnaire of Overactive bladder (OAB) and incontinence at 4 weeks
2. Urinary incontinence grade score at 4 weeks
3. Quality of life assessment (Barthel Index) at 4 weeks

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Stroke Patients diagnosed according to criteria of cerebral arterial thrombosis in Western medicine and the criteria of apoplexy in Chinese medicine
2. Inpatients who suffered a stroke in the previous 4-24 weeks
3. Male or female, aged 40-70
4. Fit the description for the syndrome of deficiency of kidney-yang or the syndrome of deficiency of qi
5. Urination disorders occuring after the stroke, and the patients' condition is stable
5.1. Patients that suffer from urinary incontinence; or

5.2. No urinary incontinence but with serious urgency of urination and increased urinary frequency
6. Patients with no disorder of consciousness, no barriers to communication
7. Patients with normal cognitive function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with severe primary diseases of the cardiovascular system, liver, kidney, hematopoietic system, psychopathy or late stage tumor
2. Patients with chronic retention of urine, urinary incontinence, urgency of urination and high frequency of urination before the stroke
3. Patients suffering from chronic urinary infection
4. Patients suffering from serious anepia, difficulty communicating or severe cognitive disorder which may result in urination disorder
5. Female with stress incontinence

Date of first enrolment
01/08/2009

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine
Beijing
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Sponsor information

Organisation
Beijing Municipal Science and Technology Commission (China)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration