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Evaluation of moxibustion therapy for urge urinary incontinence after stroke

Submission date
05/12/2013

Recruitment status
No longer recruiting

Registration date
31/12/2013

Overall study status
Completed

Last Edited
27/10/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Urge Urinary Incontinence (UUI) is a urine leakage issue, out of your control, accompanied or preceded by urgency. As a common complication of stroke, UUI results in low quality of life, high costs and burden for the nursing. Nowadays, there are several treatment options: drug treatment, behavioral therapy, surgical methods and electrical stimulation. Besides, moxibustion therapy has been applied to treat UUI after stroke for a long time in China. Our previous study shows positive effect in relieving urinary incontinence symptoms and improving quality of life. The purpose of this study is to evaluate the impact of moxibustion volume on therapeutic effect and find out the long-term follow-up effects.

Who can participate?
Patients with urge urinary incontinence after stroke are eligible to participate in this study.

What does the study involve?
During the first visit, the researcher will describe the project to the patients in detail. Eligible patients will sign a written consent form. Biochemical and physical examinations will be undertaken by qualified doctors. Participants will be randomly allocated to three groups. Group A will receive daily moxibustion therapy with moxa cones and routine care for 4 weeks. Group B will receive daily moxibustion therapy with moxibustion boxes and routine care for 4 weeks. Group C will only receive routine care for 4 weeks. Patients quality of life will be assessed at the start of the study, 4th and 16th week after treatment.

What are the possible benefits and risks of participating?
Participants may benefit from relief of symptoms and improvement in quality of life after treatment. All participants will receive moxibustion therapy for free. Conclusion obtained from this study may benefit the patients with urge incontinence after stroke in the future. The moxibustion therapy is safe based on previous clinical practice and studies. No significant risks have been identified, except for potential allergies caused by the smoke.

Where is the study run from?
This study is conducted from the following centers in China:
1. Beijing Hospital of Traditional Chinese Medicine

2. Beijing Huguosi Hospital of Traditional Chinese Medicine
3. China Rehabilitation Research Center

When is study starting and how long is it expected to run for?
The study started in January 2013 and expected to run until December 2014.

Who is funding the study?
Special project for the national clinical research bases construction belonging to the State Administration of Traditional Chinese Medicine (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
JD2X2012152

Study information

Scientific Title
Evaluation of moxibustion therapy for urge urinary incontinence after stroke: a multicenter, randomized, single-blinded, controlled clinical trial

Study objectives
Results of our preliminary study indicated that ginger-salt-partitioned moxibustion could increase the mean volume of each micturition, decrease the average daily frequency of urination and the number of toilet visits at night. In the present study, comparing with moxa cones alone, we will use moxibustion boxes with moxa sticks to increase the moxibustion volume and demonstrate whether the increased moxibustion volume could improve the clinical effects. Moreover, assessment of outcomes at 12th week as a follow-up aims to evaluate the long-term effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine, 11/11/2013, ref: 2013BL-094

Study design
Multicenter randomized single-blinded controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urge urinary incontinence after stroke

Interventions
The 120 participants will be randomly allocated to three different groups:
1. Group A will receive traditional moxibustion therapy and routine care once a day for 4 weeks. Firstly, a certain amount of salt will be put on the navel to cover the Shenque acupoint (CV-8). Secondly, the Shenque acupoint will be covered by a piece of fresh ginger slice (thickness 4-5 mm). Thirdly, a 30 mm (length) ~30 mm (diameter) moxa cone (Tongrentang Inc., China) will be placed on the fresh ginger slice. Finally, the moxa cone will be lit by the therapist. When the moxa cone is burnt out, the therapist will remove the whole moxa cone and replace it with another one. Each session requires three units of moxa cone.
2. Group B will receive new-type moxibustion therapy plus routine care once a day for 4 weeks. Common practices are the same as group A. The different manipulation is that a double-holes moxa box (13 x 8 x 8.5 cm in volume) with two 70 mm (length) ~15 mm (diameter) moxa sticks in the holes will be placed on the fresh ginger slice. The moxa sticks will be replaced. Each session requires three units of moxa cone.
3. Group C will receive routine care for cerebral vascular disease for 4 weeks only.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The mean volume of each micturition will be assessed at the baseline and at the end of the 4th and the 16th week after randomization

Key secondary outcome(s))
1. The average daily frequency of urination
2. The number of toilet visits at night
3. Quality of life assessment measured by completion of the Incontinence Quality of Life Questionnaire (I-QOL) Chinese version and the Batherl Index (BI) Chinese version

The secondary outcome measures above will be assessed at baseline and at the end of the 4th and the 16th week after randomization

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Male or female, age between 40 and 75 years
2. In-patients with urge urinary incontinence after stroke, according to the diagnosis criteria of the American Stroke Association (ASA) and the International Continence Society (ICS)
3. 4th to 48th week after stroke onset
4. Urge urinary incontinence occurring after stroke onset, or obvious urgent or frequent micturition instead of urinary incontinence
5. Normal consciousness, communication ability and recognition
6. Provided written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Insufficiency of heart, liver, kidney or other important organs
2. Chronic urinary retention or urinary incontinence before stroke
3. Urge urinary incontinence caused by spinal injury or other diseases
4. Stress urinary incontinence or chronic urinary tract infection
5. Obvious urgent or frequent micturition pre-stroke, due to hyperplasia of prostate gland

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
China

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

Sponsor information

Organisation
Project for national clinical research bases construction of State Administration of TCM (China)

Funder(s)

Funder type
Government

Funder Name
Special project for the national clinical research bases construction belonging to the State Administration of Traditional Chinese Medicine (China)

Results and Publications

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	21/10/2014		Yes	No