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A clinical study to assess the influence of acupuncturing “Wang’s Jiaji” acupoints on limb spasticity of patients in convalescent stage of ischemic stroke

Submission date
29/08/2017

Recruitment status
No longer recruiting

Registration date
21/09/2017

Overall study status
Completed

Last Edited
15/07/2019

Condition category
Circulatory System

[X] 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
Spasticity is a condition in which certain muscles are continuously contracted, causing stiffness or tightness. It is one of the most common complications of stroke, usually occurring in the convalescent (recovery) stage 1-6 months after stroke. Spasticity harms the recovery of motor function and causes malformation, thus damaging the daily living abilities of patients and increasing the caring burden for family and society. The aim of this study is to assess the effect of acupuncturing “Wang’s Jiaji” acupoints on spasticity after stroke.

Who can participate?
Patients between 40 and 75 years old in the convalescent stage of ischemic stroke

What does the study involve?
Participants are randomly allocated to one of two groups. All of the participants are given basic treatment according to the guidelines. The treatment group receive acupuncture treatment once a day 5 times per week for two weeks. The control group take the drug baclofen 3 times a day for two weeks. Upper and lower limb motor function of the affected side is assessed at the start of the study and 2, 4 and 12 weeks later.

What are the possible benefits and risks of participating?
It is expected that participants will experience lower frequency and severity of limb spasticity as well as improved motor function and strength, thus improving quality of life and avoiding the side effects of drugs and operations. Furthermore, the evidence gained from this study will be helpful in future research projects. The risks of taking part are minimal. Acupuncture is a very safe treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or experience a temporary increase in pain either during or after treatment. Participants are warned of these potential side effects before consenting to have acupuncture.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University (China)

When is the study starting and how long is it expected to run for?
January 2017 to December 2018

Who is funding the study?
Beijing Municipal Health and Family Planning Commission (China)

Who is the main contact?
Ms Huanqin Li

Contact information

Type(s)
Scientific

Contact name
Ms Huanqin Li

Contact details
Backstreet Gallery No. 23 in Dongcheng District
Beijing
China
100010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A clinical study to assess the influence of acupuncturing “Wang’s Jiaji” acupoints on limb spasticity of patients in convalescent stage of ischemic stroke

Study objectives
Compared with taking baclofen, acupuncturing “Wang’s Jiaji” acupoints can improve limb spasticity of patients in convalescent stage of ischemic stroke equally or better.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 27/01/2017, ref: 2016BL-090-02

Study design
Randomised controlled trial

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 use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Ischemic stroke

Interventions
A total of 100 participants will be randomly assigned to two different groups. All of the patients will be given basic treatment according to the guideline for prevention and treatment of cerebrovascular diseases.

Treatment group: “Wang’s Jiaji” acupoints including 16 acupoints 3 cun away from beneath the second, fourth, sixth, eighth, tenth, twelfth spinous process of thoracic vertebra and the second, fourth spinous process of lumbar vertebra. Operation: patients in lateral position, affected extremities up. Needles are inserted 25 mm in depth on these 16 acupoints until feeling tactile sensation then manually manipulated by rotation methods to produce a characteristic sensation known as "De Qi". Technique: mild reinforcing and attenuating,retaining the needle for 30 minutes. When all the needles inserted, needle handles need to be a line horizontally and vertically. The treatment will be given once a day and 5 times a week in weekdays, the course lasts two weeks.

Control group: Participants will take baclofen 5mg per time and 3 times a day, the dose may increase to 10mg per time according to level of spasticity. The course lasts two weeks.

Intervention Type
Other

Primary outcome measure
Upper and lower limb motor function of affected side, assessed using Simplified Fugl-Meyer (FMA) at baseline, 2 weeks, 4 weeks and 12 weeks after first acupuncture

Secondary outcome measures
1. Muscular tension assessed using Modified Ashworth scale at baseline, 2 weeks, 4 weeks and 12 weeks after first acupuncture
2. The ability of daily living assessed using Modified Barthel scale at baseline,2 weeks,4 weeks and 12 weeks after first acupuncture
3. The level of spasticity assessed using electromyography at baseline and 12 weeks after first acupuncture

Overall study start date
28/01/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Meet the western medicine diagnostic criterion: American Heart Association/American Stroke Association, AHA/ASA in 2013
2. Patients with cerebral infarction and the session is between 1 month and 6 months
3. Patients between 40 and 75 years old. Patients over 75 can also be accepted in the trial if the doctor approves the significance of rehabilitation therapy after assessment, but all the patients should not be over 80 years old
4. 4 points ≤ NIHSS ≤21 points
5. 2 grade ≤ MAS ≤4 grade
6. GCS ≥7 points without any consciousness trouble
7. First attack of stroke or not for the first time without any serious disabilities, mRS ≤3 points
8. Confirmed by head CT or MRI
9. Patients who agreed to participant in this trial and assigned the informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients with limb dystonia caused by cerebral or other diseases
2. Patients participated in other trials within 3 months
3. Patients with serious heart,liver,kidney and hematopoietic system diseases or mental disorders
4. Taking drugs for improving muscular tension apart from baclofen

5. Afraid of acupuncture or allergic to baclofen
6. Women in pregnant or lactating period
7. Patients with congenital disability

Date of first enrolment
01/11/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University
Backstreet Gallery No. 23 in Dongcheng District
Beijing
China
100010

Sponsor information

Organisation
Beijing Municipal Health and Family Planning Commission

Sponsor details
North Latitude Road No. 59
Beijing
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

Publication and dissemination plan
The trialists plan to publish the protocol about 6-8 months after registration and publish the results 2 years after the end of the trial.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Huanqin Li. About two years after the end of this trial and open publication of the result, the primary data and type of analysis will be available for 5-10 years until the data is updated by a more specific study with a larger number of participants. Anyone interested in the trial can ask to share the primary data by sending a requirement through email. Collected primary data is provided without the private information of participants, all the data sequence will be numbered instead of real names.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/07/2019	15/07/2019	Yes	No