ISRCTN22214747 https://doi.org/10.1186/ISRCTN22214747

The effect of acupuncture for constipation after ischemic stroke

Submission date 14/06/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/06/2015	**Overall study status** Completed	
Last Edited 24/08/2018	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Stroke is the second leading cause of death and disability among adults worldwide and the prevalence is still increasing. Constipation is one of the most common complications after stroke that severely influences patients' quality of life and their rehabilitation. Studies indicate that about 30% to 60% of stroke patients have suffered from constipation after stroke. Although treatments for constipation are varied, many of them are difficult to tolerate or are rejected because of adverse events, or have not been proven to be effective. Acupuncture may be effective for constipation but studies focusing on acupuncture for constipation after stroke are rare. The aim of this study is to compare the effectiveness of acupuncture, mosapride citrate tablet and routine health care in patients with constipation after ischemic stroke.

Who can participate?
Patients aged between 30 and 75 diagnosed with ischemic stroke with symptoms of constipation.

What does the study involve?
Participants will be randomly allocated into one of three groups. The first group will be treated with acupuncture. They will receive 16 treatment sessions over 4 weeks. Each session will last for 30 minutes. The second group will take a mosapride citrate tablet three times a day for 4 weeks. The third group will receive routine treatment and healthcare for ischemic stroke.

What are the possible benefits and risks of participating?
The participants' symptoms of constipation may be improved by participating in the study. The results of the study will help clinicians select more effective treatments for constipation. Participants may feel soreness, numbness, distension or heaviness around the acupuncture points. If the following events occur, they will be regarded as adverse events and the researchers will treat the participants with relevant conventional therapy, or even hospitalize them. The adverse events include local hematoma (a solid swelling of clotted blood), breaking of needle, retained needle after treatment, fainting, unbearable prickling, severe pain or discomfort persisting more than 1 hour after acupuncture, local infection and abscess, diarrhea, abdominal pain, and hives.

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?
From December 2015 to July 2018.

Who is funding the study?
Beijing Municipal Science and Technology Commission, Beijing Municipal Administration of Hospitals, Ministry of Science and Technology of the People's Republic of China and State Administration of Traditional Chinese Medicine of the People's Republic of China.

Who is the main contact?
Dr Tao Zhang

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of acupuncture versus mosapride citrate tablet versus routine health care in improving spontaneous bowel movements, stool consistency and straining during defecation in patients with constipation after ischemic stroke: a single-centre randomised controlled trial

Study objectives
Acupuncture is effective for constipation after ischemic stroke. The effect of acupuncture is at least equivalent to mosapride citrate table but is better than conventional health care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 09/07/2015, ref: 2015BL-041-01

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Constipation after ischemic stroke

Interventions
1. Acupuncture group: acupuncture point selection: CV13 (Shangwan), CV12 (Zhongwan), CV10 (Xiawan), bilateral ST25 (Tianshu), CV6 (Qihai), bilateral PC6 (Neiguan) and bilateral ST36 (Zusanli). Each session will last for 30 minutes. Every participant will be treated once a day and will receive 16 treatment sessions in total during 4 continuous weeks. Treatment will be conducted 5 times per week in the first 2 weeks and 3 times per week in the last 2 weeks.
2. Medicine group: mosapride citrate tablet will be taken orally at the dose of 5 mg, three times a day for 4 weeks continuously.
3. Control group: participants of control group only receive routine treatment and healthcare for ischemic stroke. For participants who have had no bowel movements over 4 or more consecutive days, a cathartic will be used as an emergency drug.

Intervention Type
Mixed

Primary outcome measure
The change of mean weekly complete spontaneous bowel movements (CSBMs) from baseline; measured at the 4th and the 8th week after randomisation

Secondary outcome measures
1. The change of mean weekly spontaneous bowel movements (SBMs) from baseline, measured at the 4th and the 8th week after randomisation
2. The change of mean scores of stool consistency from baseline, measured at the 4th and the 8th week after randomisation
3. The change of mean scores of straining during defecation from baseline, measured at the 4th and the 8th week after randomisation
4. The change of weekly frequency of using laxatives from baseline, measured at the 4th and the 8th week after randomisation

Overall study start date
01/12/2015

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Diagnosed with ischemic stroke according to the diagnostic criteria specified by the World Health Organization (WHO)
2. With symptoms of constipation according to the Rome III functional constipation criteria
3. 2 weeks to 6 months after stroke onset
4. Aged between 30 and 75 years old, either gender
5. The Glasgow Coma Scale (GCS) score ≥ 7 and the National Institute of Health Stroke Scale (NIHSS) ≤ 21, which indicates that participants are conscious and without dysfunctions in comprehension
6. With no previous medical history of constipation before stroke onset and the symptoms of constipation present at least 2 weeks continuously after stroke
7. No use of gastrointestinal drugs 1 week before randomisation (except for emergency drugs)
8. No acupuncture treatment for constipation in the previous 2 weeks
9. Volunteered to join the clinical trial and provided a signed informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 participants in total and 40 participants in every group.

Key exclusion criteria
1. Irritable bowel syndrome (IBS) and constipation secondary to organic diseases (for example, endocrine, metabolic or postoperative diseases) or drugs
2. Participants with abdominal aneurysm, hepatosplenomegaly, serious cardiovascular, liver, kidney or psychiatric disease, or severe dystrophy who cannot cooperate to be examined or

treated
3. Pregnant women or women in lactation
4. Blood coagulation disorders, or administration of anticoagulant agents such as warfarin and heparin (participants treated with antiplatelet treatment such as asprin or clopidogrel as secondary prevention of cerebral infarction are eligible)

Date of first enrolment
01/12/2015

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
No.23 Meishuguanhoujie
Dongcheng District
Beijing
China
100010

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University

Sponsor details
No. 23 Meishuguanhoujie
Beijing
China
100010

Sponsor type
Hospital/treatment centre

Website
http://www.bjzhongyi.com/

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and Technology Commission

Funder Name
Beijing Municipal Administration of Hospitals

Funder Name
Ministry of Science and Technology of the People's Republic of China

Alternative Name(s)
Chinese Ministry of Science and Technology, Ministry of Science & Technology, People Republic of China, , Ministry of Science and Technology (China), State Science and Technology Commission, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
State Administration of Traditional Chinese Medicine of the People's Republic of China

Alternative Name(s)
State Administration of Traditional Chinese Medicine, State Administration of TCM, SATCM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
The result of this study will be disseminated via peer-reviewed publications and conference presentations.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/08/2018		Yes	No