ISRCTN68981054 https://doi.org/10.1186/ISRCTN68981054

Treatment of dysphagia after stroke with He's santong needling method

Submission date 13/09/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/09/2017	**Overall study status** Completed	
Last Edited 07/09/2018	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Dysphagia (difficulties swallowing) is common after stroke, with multiple complications such as pneumonia (lung inflammation), dyspepsia (indigestion) and dehydration. The aim of this study is to assess the effectiveness of He’s santong needling method acupuncture compared with a swallowing rehabilitation training program for dysphagia after stroke.

Who can participate?
Patients with dysphagia after stroke

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group receive He's santong needling method acupuncture (2-5 30-minute sessions per week) combined with swallowing rehabilitation, while participants in the other group are treated with swallowing rehabilitation (5 sessions per week). All participants are given 4 weeks of treatment. Swallowing function is assessed at the start of the study and after 4 weeks.

What are the possible benefits and risks of participating?
In addition to basic treatment, the participants receive He’s santong needling method acupuncture which may promote the recovery of swallowing function after stroke. Information obtained from this study may benefit patients with the same condition in the future. During acupuncture, the patients may experience brief pain or soreness, and other possible problems include bleeding, ecchymosis (discoloration of the skin) or paresthesia (prickling or burning) around the spot of the needle.

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

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Beijing Traditional Chinese Medicine Administration Administrative Project (China)

Who is the main contact?
1. Dr Bin Li
libin@bjzhongyi.com
2. Mr Luo-peng Zhao
zhao_luopeng@163.com

Contact information

Type(s)
Public

Contact name
Dr Bin Li

Contact details
Beijing Dongcheng District Backstreet Gallery No.23
Beijing
China
100010
+86 (0)18910781852
libin@bjzhongyi.com

Type(s)
Public

Contact name
Mr Luo-peng Zhao

Contact details
Beijing Dongcheng District Backstreet Gallery No.23
Beijing
China
100010
+86 (0)17888808581
zhao_luopeng@163.com

Additional identifiers

Protocol serial number
000000

Study information

Scientific Title
Treatment of dysphagia after stroke with He's santong needling method: a prospective randomized controlled study

Study objectives
This is a prospective randomized controlled study to evaluate the efficacy of He's santong needling method acupuncture compared with swallowing rehabilitation in dysphagia after stroke.

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, 09/05/2017, ref: 2017BL-013-02

Study design
Prospective randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dysphagia after stroke

Interventions
A total of 60 volunteers will be recruited and randomly divided into two groups.

The treatment group will receive He's santong needling method acupuncture, consisting of 2-5 30-minute sessions per week, administered over 4 weeks, combined with swallowing rehabilitation given over 5 sessions per week. Acupuncture points were selected based on the consensus of clinical experiences of acupuncture experts including GB20(fengchi), HT5 (tongli), GV16 (fengfu), TE17 (yifeng), CV23 (liquan), jialianquan, ST40 (fenglong), EX-HN12 (jinjin), EX-HN13 (yuye) and yanhoubi.

The control group will be treated with swallowing rehabilitation for 4 weeks (5 sessions/per week), consisting of preparation phase, swallowing functional training and food swallowing training.

Intervention Type
Other

Primary outcome(s)
The dynamics of swallowing function, measured using FEES (Fiberoptic Endoscopic examination of Swallowing) and Caiteng 7 Rank (CT7R) at baseline and 4 weeks

Key secondary outcome(s))
1. Quality of life in patients with dysphagia, measured using SWAL-QOL (Swallowing-Related Quality of Life) at baseline and 4 weeks
2. Swallowing ability, measured using MMASA (The Modified Mann Assessment of Swallowing

Ability) at baseline and 4 weeks
3. Function of swallowing muscle, measured using sEMG (Surface Electromyography) at baseline and 4 weeks

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Meet the diagnosis criteria of stroke according to “Chinese Cerebrovascular Disease Prevention And Treatment Guidelines (2005)” and are confirmed by head CT or MRI
2. Watian swallowing test score: 3-5
3. Dysphagia during oral and pharyngeal phases
4. Can understand and perform simple instructions issued by the therapist, the abbreviated mental test (AMT) score >7, can cooperate and sit up for 30 minutes alone or with the help
5. Have a good compliance with the observation and evaluation of the researchers and volunteer to complete the tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Have a history of swallowing disease or other diseases that affect swallowing such as Myasthenia gravis, Guillain-Barre, head esophageal neoplasms
2. Mental illness and severe heart, lung, or kidney disease
3. Disturbance of consciousness and cognitive impairment, the abbreviated mental test (AMT) score <=7
4. With cardiac pacemaker, metal implants or orthosis, head or neck skin damage, have an allergy to the electrode

Date of first enrolment
17/10/2017

Date of final enrolment
17/10/2019

Locations

Countries of recruitment
China

Study participating centre
Luo-peng Zhao
China
100010

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine affiliated to the Capital Medical University

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

Funder Name
Beijing Traditional Chinese Medicine Administration Administrative Project

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/08/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes