

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

Submission date 13/09/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/09/2018	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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?

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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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

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2017

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

Age group

Adult

Sex

Both

Target number of participants

60

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

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Sponsor information

Organisation

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

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/057vq6e26>

Funder(s)

Funder type

Government

Funder Name

Beijing Traditional Chinese Medicine Administration Administrative Project

Results and Publications

Publication and dissemination plan

Outcomes of the trial will be disseminated through peer-reviewed publications. The trialists intend to publish the study protocol by 31/12/2017 and publish the study research data and conclusion on dysphagia after stroke by 31/12/2020.

Intention to publish date

31/12/2020

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