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Treatment effects of an electro-acupuncture therapy on stress urinary incontinence

Submission date
29/06/2024

Recruitment status
No longer recruiting

Registration date
19/07/2024

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol
Background and study aims
This study aimed to optimise the treatment of stress urinary incontinence (SUI) using electroacupuncture and investigate the effect of electroacupuncture therapy targeted at the sacral and abdominal acupoints among patients with SUI. Stress incontinence happens when movement or activity puts pressure on the bladder, causing urine to leak. Electroacupuncture is a type of acupuncture where a small electric current is passed between pairs of acupuncture needles.

Who can participate?
Female patients aged 30-75 years with stress urinary incontinence (SUI)

What does the study involve?
Participants were randomly divided into three groups, a pelvic floor muscle training (PFMT) group, PFMT + sacral acupoint group and PFMT + sacral acupoint + abdominal acupoint group. The effects of treatment in the three groups were compared at 3 months.

What are the possible benefits and risks of participating?
SUI treatment with electroacupuncture stimulating the sacral-abdominal acupoint combined with PFMT helps patients reduce related clinical symptoms and improves their quality of life.

Where is the study run from?
Luohu Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
April 2021 to January 2023

Who is funding the study?
Guangdong Provincial Bureau of Traditional Chinese Medicine (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Stress urinary incontinence treatment effect of electroacupuncture therapy targeted at sacral and abdominal acupoints in female patients

Study objectives
Stress urinary incontinence (SUI) treatment with electroacupuncture stimulating the sacral-abdominal acupoint combining pelvic floor muscle training (PFMT) has certain advantages in reducing International Consultation on Incontinence Questionnaire - Short Form (ICI-Q-SF) score, reducing urinary incontinence frequency, and enhancing pelvic floor muscle strength, which helps patients to reduce related clinical symptoms and improve their quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/05/2021, Ethics Committee of Luohu Hospital of Traditional Chinese Medicine (No. 16 of Xiantong Street, Luohu District, Shenzhen, 518000, China; +86 (0)755 8231 1522; lhqzyybgs@163.com), ref: 2021051910

Study design
Single-centre double-blinded interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stress urinary incontinence (SUI)

Interventions
According to the random number table method, participants were divided into three groups: PFMT, PFMT + sacral, and PFMT + sacral + abdominal points, with 52 cases in each group.

Although the PFMT group received regular PFMT, patients in the PFMT + sacral acupoint group were treated by combining PFMT with electroacupuncture at the Huiyang, Zhonglüshu and Zhongliao acupoints in the sacral region. For patients in the PFMT + sacral acupoint + abdominal acupoint group, the Qihai, Zigong and Zhongji acupoints in the abdominal region were also involved.

Patients in the PMFT group performed the following exercises:
1. Kegel exercises: puerperae lay in a horizontal position breathing deeply and in a relaxed manner with flexion and the separation of both legs. During inhalation, they needed to contract the anus and urethra for 2–3 seconds without interruption. This action was repeated for 5–10 minutes once or twice a day. According to the patient's tolerance, the duration and frequency of the Kegel exercises could be adjusted and gradually increased. The longest duration of a single anus and urethra contraction was 5–10 seconds, and each exercise lasted for a maximum of 10–15 minutes.
2. Vaginal dumbbell training: Vaginal dumbbells suitable for the respective participants were selected based on their pelvic floor muscle strength testing results. As directed, the patients were asked to insert the vaginal dumbbell approximately 2 cm deep into the vagina and hold the dumbbell through muscle contraction. They then tried different body positions, including standing, sitting and climbing stairs (10–15 minutes at a time once a day). The above exercises were continued for 2 months.

In addition to PFMT, patients in the PFMT + sacral acupoint group underwent electroacupuncture at the Huiyang, Zhonglüshu and Zhongliao acupoints in the sacral region.

Patients in the PFMT + sacral acupoint + abdominal acupoint group also received electroacupuncture at the Qihai, Zigong and Zhongji abdominal acupoints. Specific manipulations are as follows.

The participants were asked to empty their bladders before treatment. During the course of abdominal acupuncture, patients were in a supine position, and corresponding acupuncture sites were sterilised using routine methods. Hwato Disposable Acupuncture Needles (0.35 × 40 mm) were utilised for acupuncture in an oblique direction from the Qihai to Guanyuan acupoints for 35 mm and from the Zhongji to Qugu acupoints for 35 mm but in a straight direction at the Zigong acupoint for 25 mm. As qi is induced by acupuncture, the needle was manipulated using a uniform reinforcing–reducing method. Subsequently, the Hwato SDZ-II Electroacupuncture Apparatus was adopted to randomly connect two acupoints each time using dilatational waves, a frequency of 2/15Hz and intensity of 5 mA, all of which could be adjusted according to the patient's tolerance. The treatment was considered appropriate as long as the patients felt comfortable. This treatment continued for 30 minutes each time. During sacral acupuncture, patients were placed in a prone position, and their acupuncture sites were routinely disinfected. Hwato Disposable Acupuncture Needles (0.35 × 40 mm) were again selected for acupuncture in an oblique direction from Huiyang to Zhonglüshu for 4–5 cm, then in a straight direction from the Zhonglüshu acupoint for 4–5 cm and obliquely upward at the Zhongliao acupoint for 4–5 cm. Through the above manipulations, a needling sensation should be continuously felt in the perineum and urinary tract region. Subsequently, an electric acupuncture device was connected. Each time, two acupoints were selected on each side of the body. The parameters configured for this device were the same as those described above. This treatment also lasted for 30 minutes, and each course of treatment was conducted once every 2 days and lasted for a period of 2 months.

Intervention Type
Supplement

Primary outcome measure
Measured at 6 weeks of treatment and 3 months follow up after treatment:
1. Basic patient information (age, height, body mass index, educational level, past medical history and delivery mode) measured using questionnaires
2. 1-hour pad test results measured by pad test

Secondary outcome measures
1. 1-hour pad test results measured by pad test at 2 weeks 4 weeks, 6 weeks of treatment and 18 weeks follow up after treatment
2. Times of urinary incontinence measured using International Consultation on Incontinence Questionnaire—Short Form (ICI-Q-SF) scores before treatment, during the 1-6 weeks of treatment and at 15-18 weeks follow up after treatment
3. Quality of life measured using Incontinence Quality of Life Instrument (I-QOL) scores before treatment, during the 1-6 weeks of treatment and at 15-18 weeks follow up after treatment
4. 72-hour urinary incontinence frequencies measured using pad test before treatment, during the 1-6 weeks of treatment and at 15-18 weeks follow up after treatment
5. Average pad usage per week measured using pad test before treatment, during the 1-6 weeks of treatment and at 15-18 weeks follow up after treatment

Overall study start date
01/04/2021

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Female patients aged 30–75 years
2. Patients with symptoms conforming to the diagnosis standards of mild and moderate SUI
3. Patients conforming to the syndrome differentiation standards of urinary incontinence caused by kidney qi deficiency
4. Patients with normal routine examination results including those for urine and negative urine culture tests

Participant type(s)
Patient

Age group
Adult

Lower age limit
30 Years

Upper age limit
75 Years

Sex
Female

Target number of participants
200

Total final enrolment
156

Key exclusion criteria
1. Patients with urge urinary incontinence or mixed urinary incontinence
2. Patients with a medical history of surgical treatment for urinary incontinence or pelvic surgery
3. Patients with uterine prolapse severity ≥Grade 2
4. Patients with symptomatic urinary system infection
5. Patients with residual urine volumes >30 ml
6. Patients with maximum uroflow rates <20 ml/s
7. Patients incapable of or with restricted capacity for walking, going upstairs/downstairs or running
8. Patients taking drugs that may affect their bladder function or receiving specific SUI treatment
9. Patients with SUI combined with multiple system atrophy, cauda equina lesions or myeleterosis
10. Patients who were pregnant or lactating

11. Patients fitted with cardiac pacemakers, sensitive to metals or with severe enetophobia
12. Patients with pelvic prolapse

Date of first enrolment
01/06/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
China

Study participating centre
Luohu Hospital of Traditional Chinese Medicine
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
Guangdong Provincial Bureau of Traditional Chinese Medicine research project

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Na-na Zhao (zhaonana3131@163.com).

IPD sharing plan summary
Available on request