Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Efficacy of Electro-acupuncture with Kinesiotape Compared to Biofeedback for Controlling Urinary Symptoms in Patients with Urinary Incontinence

Protocol summary

Study aim

Comparison of the therapeutic effect of electroacupuncture with kinesiotape in comparison with biofeedback in controlling the symptoms of patients with stress, urgency and mixed urinary incontinence in patients aged 20-80 years referred to Mahdieh Hospital.

Design

Clinical trial, with two intervention groups, with parallel groups, one-way blind, randomized, on 60 patients, block randomization method based on statistical equations was used for randomization.

Settings and conduct

Randomized clinical trial is a single-blind study performed on patients with stress, urgency and mixed incontinence referred to Mahdieh Hospital. Patients were randomly divided into two groups, neither of which knew about the intervention process of the other group.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Women with stress, urgency and mixed urinary incontinence in the age range of 20-80 years, who have had symptoms for at least three months, and are referred by gynecologists, general surgeons and urologists. Exclusion criteria:Patients with , upper motor neuron disease, such as cerebral palsy, multiple sclerosis, spinal cord injury, stroke, recent perineal Truman(less than 3 month ago), history of genital surgery and diabetes mellitus.

Intervention groups

The first group is treated with electroacupuncture and kinesiotype for 5 sessions of 20 minutes (including 10 minutes of continuous stimulation and 10 minutes of pulse). The second group is treated with biofeedback for 5 sessions of 20 minutes with a protocol of 10 minutes of electrical stimulation each session and then 10 minutes of active strengthening of the pelvic floor muscles through a rectal probe with due regard to health issues.

Main outcome variables

Improvement percentage of urinary incontinence, nocturia, urgent urinary incontinence, stress urinary incontinence

General information

Reason for update

To whom it may be a concern, Due to the Covid-19 pandemic, we could not recruit eligible participants for the study based on the recorded dates in the primary protocol. In this study, the actual recruitment dates were modified and reported in the updated version of the protocol. Thank you very much for your kind attention. Regards, Dr. Mousavi

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050979N1**
Registration date: **2022-06-06, 1401/03/16**
Registration timing: **prospective**

Last update: **2022-11-19, 1401/08/28**
Update count: **2**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Sajede Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01
Expected recruitment end date
2022-07-23, 1401/05/01
Actual recruitment start date
2022-06-10, 1401/03/20
Actual recruitment end date
2022-07-10, 1401/04/19
Trial completion date
2022-09-10, 1401/06/19

Scientific title
The Efficacy of Electro-acupuncture with Kinesiotape Compared to Biofeedback for Controlling Urinary Symptoms in Patients with Urinary Incontinence

Public title
The Efficacy of Electro-acupuncture with Kinesiotape in Patients with Urinary Incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with urinary stress or urgent incontinence Patients with a history of at least three months of urinary incontinence complications Women aged between 20 to 80 years
Exclusion criteria:
Patients with , upper motor neuron disease, such as cerebral palsy, multiple sclerosis, Stroke, spinal cord injury Recent perineal trauma(Less than three months ago) History of genital surgery diabetes mellitus
Age
From **20 years** old to **80 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **43**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial study, 60 patients with complications related to urinary incontinence will be included in the study. For random allocation of individuals in the study groups (intervention group and comparison group), the method of random allocation with block method (Block Randomization) will be used. In this method, blocks with a size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1:1 will be used. Random Allocation software will be used to generate random sequences. The random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified on the cards and these cards are placed inside the sealed envelopes in order. In order to maintain the created sequence, the numbering will be recorded on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants would not be aware of the intervention and control groups in this study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid A'rabi street, Yemen blvd, Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
1185817311
Approval date
2021-01-31, 1399/11/12
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.1011

Health conditions studied

1

Description of health condition studied
Stress incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress incontinence (female) (male)

2

Description of health condition studied
Urge incontinence
ICD-10 code
N39.41
ICD-10 code description
Urge incontinence

Primary outcomes

1

Description
Improvement percentage in urinary incontinence
Timepoint
Before, After treatment, 2 months after treatment
Method of measurement
International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS)

Secondary outcomes

empty

Intervention groups

1

Description
People in the first group are treated with electroacupuncture for 5 sessions for 20 minutes. During this period, patients are subjected to continuous stimulation for 10 minutes and pulsed stimulation for 10 minutes via an acupuncture needle. 4 needles are placed at the same distance from the ASIS area to the tubercle pubic area. The needles are spaced from the pulse of the artery. At the end of each treatment session, all members of this group are treated with pelvic floor kinesiotype. Pelvic floor typing is from pubic tubercle to ASIS, which is without tension on both sides and 50% in the middle with tension. All patients were instructed in how to care for the kinesiotype, and did not separate the kinesiotype until the next treatment session.
Category
Treatment - Other

2

Description
The second group is treated with biofeedback for 5 sessions of 20 minutes, which includes 10 minutes of electrical stimulation and 10 minutes of active muscle contraction with auditory and visual feedback. These stimulations are applied through a rectal probe in accordance with health standards.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdie Hospital in Tehran
Full name of responsible person
Parvin Momeni
Street address
Rajabnia street, Shishegar khane alley, Fadaeian-e-eslam street, Shoush square
City
Tehran
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sajede.mousavi72@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Deputy of research and technology, Shahid Beheshti University of Medical Sciences, Shahid Abbas A'rabi street, Yemen street
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Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Najme Sadat Bolandnazar
Position

Associate professor

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available