

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Mahdiah 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 Mahdiah 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 kinesiotape 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)

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+98 51 5229 2936

Email address

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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

AgeFrom **20 years** old to **80 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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

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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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Latest degree

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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