

# 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 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)

###### Phone

+98 51 5229 2936

###### Email address

sajede.mousavi72@gmail.com

##### 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

##### Province

Tehran

##### Postal code

1185817311

##### Phone

+98 21 5506 2628

##### Email

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1185817311

##### Phone

+98 21 2243 9781

##### Email

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

**Street address**

Shahid Rajabnia street, Shoush square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1185817311

**Phone**

+98 21 5506 2628

**Email**

sajede.mousavi72@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Najme sadat Bolandnazar

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Najme Sadat Bolandnazar

**Position**

Assistant professor

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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