Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of Parasacral Transcutaneous Electrical Nerve Stimulation in the Treatment of Patients with Overactive Bladder Syndrome: A Single Blinded Randomized Controlled Trial

Protocol summary

Study aim

Comparison of quality of life improvement related to OAB in the group treated with parasacral TENS compared to the SHAM group and pharmacological treatment, categorized by time periods before and after treatment

Design

A clinical trial with a control group, parallel groups, single-blind, randomized involving 75 patients.

Settings and conduct

Al-Zahra Women's Hospital, Tabriz - Women's Fertility Health Research Center

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Individuals aged 18 years or older with OAB. Participants must have experienced symptoms for at least three months and provide informed consent. Exclusion Criteria: Individuals with neurological disorders affecting bladder function. Patients currently receiving other pharmacological treatments for OAB or those who have recently undergone bladder surgery. Pregnant or breastfeeding women. Individuals with stress or mixed incontinence.

Intervention groups

In this study, pelvic floor muscle training exercises will be implemented for both groups using the PFMT protocol. This will last for 6 to 8 weeks, where each set includes three exercises with ten repetitions each. Additionally, Transcutaneous Electrical Nerve Stimulation (TENS) will be employed, utilizing two surface electrodes placed on the S3 and S2 areas. The study will include 24 TENS sessions conducted three times a week for 8 weeks. TENS will operate at a frequency of 10 Hz and pulse durations of 500 to 700 microseconds. In the experimental group, only the parasacral electrodes will be active, while in the SHAM group, the device will be used without current.

Main outcome variables

Changes in the severity of overactive bladder (OAB) symptoms are assessed using the following validated questionnaires: ICIQ-OAB Questionnaire -ICIQ-UI SF Questionnaire -Voiding Diary Form -LUTS-QoL Questionnaire FSFI Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241122063802N1**
Registration date: **2025-02-09, 1403/11/21**
Registration timing: **prospective**

Last update: **2025-02-09, 1403/11/21**
Update count: **0**

Registration date

2025-02-09, 1403/11/21

Registrant information

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Reza Sattarpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Parasacral Transcutaneous Electrical Nerve Stimulation in the Treatment of Patients with Overactive Bladder Syndrome: A Single Blinded Randomized Controlled Trial

Public title

Efficacy of Parasacral Transcutaneous Electrical Nerve Stimulation in the Treatment of Patients with Overactive Bladder Syndrome: A Single Blinded Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals aged 18 or older with Overactive Bladder (OAB) who have experienced urinary urgency, frequency (more than eight times a day), nocturia (waking up more than twice at night), and/or urgency urinary incontinence (an average of eight or more urinations in 24 hours and three or more urgencies, with severity levels of 3—severe urgency or 4—urgency incontinence) with or without incontinence over a period of three days. Participants must have experienced symptoms for at least three months and provide informed consent.

Exclusion criteria:

- Individuals with neurological disorders affecting bladder function - Patients currently receiving other medications for OAB or those who have recently undergone bladder surgery. Pregnant or breastfeeding women Individuals with stress or mixed incontinence Presence of a urinary catheter Evidence of a symptomatic urinary tract infection, chronic bladder inflammation, or stones Previous pelvic radiation therapy, or current malignancy Patients with implanted electronic devices (such as pacemakers) Those with active skin infections or lesions at the electrode placement site. Individuals with epilepsy or a history of seizures Patients with severe cardiac conditions or other serious systemic diseases High blood pressure is defined as systolic blood pressure (SBP) greater than 180 mmHg or diastolic blood pressure (DBP) greater than 110 mmHg.

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with overactive bladder will be randomly assigned to two separate groups using a method called Balanced Block Randomization. This method allows for random assignment in such a way that the study groups are balanced in terms of baseline characteristics, clinical variables, and all potential confounding variables. In this study, the number of blocks will be ... and the size of each block will consist of 4 patients. Essentially, the arrangement within each block indicates the type of group/intervention for each patient. Random allocation was performed using STATA software version 14 by an epidemiologist. The list of blocks and their random allocation order is attached in the Excel file (Rand).

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a randomized, single-blind, controlled clinical trial. Participants will include at least 75 patients diagnosed with overactive bladder, who will be randomly assigned by a methodologist (who will have no role in the final analysis) at the Al-Zahra Clinical Trial Center in Tabriz to one of three treatment groups: parasacral treatment, TENS, SHAM, and pharmacological treatment. The study will be blinded for the providers assessing the outcomes, while those administering the treatments will be aware of the type of treatment being given. Randomization will be carried out using a sealed, opaque envelope.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Azadi Street Golgasht Street Central Building of the University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2025-01-13, 1403/10/24

Ethics committee reference number

IR.TBZMED.REC.1403.894

Health conditions studied

1

Description of health condition studied
Overactive bladder
ICD-10 code
N32.81
ICD-10 code description
Overactive bladder

Primary outcomes

1

Description
ICIQ-OAB Score: A 4-item questionnaire with a score range of 0-16, where higher scores indicate greater severity of overactive bladder symptoms.Mild OAB: Total score of 5 or lessModerate OAB: Total score between 6 and 11Severe OAB: Total score of 12 or more.
Timepoint
Initially, 2 months and 4 months after treatment
Method of measurement
Using the valid and reliable Persian ICIQ-OAB questionnaire

2

Description
The score of the ICIQ-UI SF questionnaire: It is a 4-item questionnaire with a scoring range of 0-21. This questionnaire is used to evaluate the frequency, severity, and impact on quality of life of urinary incontinence in men and women in research and clinical practice worldwide. 0: No urinary incontinence exists. 1-5: Mild incontinence; may not have a significant impact on quality of life. 6-12: Moderate incontinence; likely affects daily activities. 13-21: Severe incontinence; has a significant impact on quality of life and daily functioning.
Timepoint
Initially, 2 months and 4 months after treatment
Method of measurement
Using the valid and reliable Persian ICIQ-UI SF questionnaire

3

Description
The LUTS-QoL questionnaire score: A 20-item questionnaire for evaluating the quality of life in individuals with urinary incontinence. The minimum and maximum scores on this questionnaire are 19 and 76, respectively, with lower scores indicating better quality of life.
Timepoint
Initially, 2 months and 4 months after treatment
Method of measurement
Using the valid and reliable Persian LUTS-QoL questionnaire

4

Description
The Female Sexual Function Index (FSFI) is a valid 19-question questionnaire that evaluates female sexual function in six domains. Higher scores indicate better sexual function. The total FSFI score is calculated by summing the scores of individual domains, with a maximum possible score of 36. Scores below 26.55 are typically considered indicative of sexual dysfunction.
Timepoint
Initially, 2 months and 4 months after treatment
Method of measurement
Using the valid and reliable Persian FSFI questionnaire

5

Description
The Voiding Diary form contains information such as the number of urination instances, the volume of urine passed, and the volume of fluids consumed by the patient over a period of at least 24 hours. The Voiding Diary form will be given to patients and they will be asked to complete it 72 hours before starting treatment (before the first therapy session) and 72 hours after completing treatment (after the last therapy session).
Timepoint
Initially, 2 months and 4 months after treatment
Method of measurement
Using the valid and reliable Persian Voiding diary

Secondary outcomes

1

Description
The occurrence and severity of any side effects related to treatment with parasacral TENS will be recorded and evaluated at the same time intervals (initially, 3 months, and 6 months after treatment). Therefore, the primary outcome of this study is the change in the severity of OAB symptoms, which will be measured using standard tools. Secondary outcomes will also include changes in quality of life and the occurrence of potential side effects resulting from the treatment.
Timepoint
Initially and at 2 and 4 months after treatment.
Method of measurement
The treatment is defined using treatment-emergent adverse events (TEAEs). A TEAE is defined as a side effect that begins after the start of the experimental drug treatment; or if the event has been ongoing from the beginning and has become serious, it is related to the experimental drug or has resulted in death, discontinuation, interruption, or reduction of the experimental treatment.

Intervention groups

1

Description

Intervention group: Intervention 1) Pelvic Floor Exercises This intervention will be the same for all groups to ensure that neither group is deprived of primary and supportive treatment. Both groups in the study will use pelvic floor muscle strengthening exercises following the protocol below. The exercises will follow the Progressive Supervised Pelvic Floor Muscle Training (PFMD) protocol, consisting of three sets throughout the day, with each set including three exercises and ten repetitions of each exercise for a duration of 6 to 8 weeks. Intervention 2) Parasacral Electrical Stimulation In this study, a device will be used for Transcutaneous Electrical Nerve Stimulation (TENS). Two surface electrodes, 3.5 centimeters in size, will be placed on each side of S3 and S2. The electrical energy will be generated by a generator. This method will consist of 24 TENS sessions. TENS will be performed three times a week for 8 weeks, with each session lasting 20 minutes. The frequency used will be 10 Hz, with pulse durations of 500-700 microseconds. The current intensity will be increased to the maximum level tolerable by the individual. In the experimental group, only the active parasacral electrodes will be used, while in the SHAM group, the device will be connected similarly without establishing current flow.

Category

Treatment - Other

2

Description

Control group: Intervention 1) Pelvic Floor Exercises This intervention will be the same for both groups to ensure that neither group is deprived of primary and supportive treatment. Both groups in the study will use pelvic floor muscle strengthening exercises following the protocol below. The exercises will follow the Progressive Supervised Pelvic Floor Muscle Training (PFMD) protocol, consisting of three sets throughout the day, with each set including three exercises and ten repetitions of each exercise for a duration of 6 to 8 weeks.

Category

Treatment - Other

3

Description

Intervention group: Mirabegron therapy group: Participants will receive a standard dose of Mirabegron (50 mg) daily."

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Women's Hospital Tabriz - Women's Reproductive Health Research Center

Full name of responsible person

Parvin Bastani

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Al-Zahra Educational and Treatment Center, Baghshamal Intersection, South Army Street

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person
Reza Sattarpour
Position
Research assisstant
Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The published data will include all the measured variables in the study while fully adhering to anonymization principles, presented in an Excel file.
When the data will become available and for how long
Access to the data will begin immediately after the publication and printing of the results.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers working in academic and scientific institutions have no specific restrictions on data analysis.
From where data/document is obtainable
To obtain study data, correspondence should be made to the following email address: rezasattarpour.tums@gmail.com.
What processes are involved for a request to access data/document
If there is a request for study data, the requester should send a proposal or details of their project via email to the responsible person. If the other researchers agree, the requested data will be provided within a maximum of two months.
Comments