

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison between Percutaneous posterior tibial nerve stimulation and Biofeedback-assisted pelvic floor muscle training on quality of life and episode of voiding in women with overactive bladder

Protocol summary

Study aim

The comparison between Percutaneous posterior tibial nerve stimulation and Biofeedback-assisted pelvic floor muscle training on quality of life and episode of voiding in women with overactive bladder

Design

This clinical trial study has two parallel groups, without blinding, randomized with closed envelopes, which is performed on 60 female patients with symptoms of bladder hyperactivity referred to the pelvic floor clinic of Rouhani Hospital in Babol.

Settings and conduct

In the biofeedback group, a vaginal electrode is placed inside the vagina and then the patient is asked to perform the desired movements. Electrical stimulation of the posterior tibial nerve, using a TENS device, one electrode is placed in the arch of the sole of the foot and the other 5 cm above the inner ankle.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study: Married female patients aged 18 to 45 years with overactive bladder. Exclusion criteria also include urinary stress incontinence, pacemaker use, cognitive impairment, superficial or deep infection at the electrode site, urinary tract infection, Neurological diseases and urinary congestion, bladder stones, prolapse of the uterus above the second degree according to the POP-Q system, pregnancy or suspected pregnancy or planning for it and cesarean delivery, uncontrolled diabetes mellitus, history of surgeries to control urinary incontinence Botulinum toxin injection.

Intervention groups

This study has two treatment groups. For the first group, pelvic floor muscles will be retrained with the help of a biofeedback device. For the second group, posterior tibial nerve electrical stimulation will be used along with Kegel exercises as in the first group.

Main outcome variables

Quality of Life; Number of daily urination; Number of nocturnal urination; Frequent urinary incontinence; Frequent sense of urgency to urinate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210624051692N1**
Registration date: **2021-09-19, 1400/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-19, 1400/06/28**

Update count: **0**

Registration date

2021-09-19, 1400/06/28

Registrant information

Name

maryam ebrahimi

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

2021-08-22, 1400/05/31

Expected recruitment end date

2021-11-28, 1400/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between Percutaneous posterior tibial nerve stimulation and Biofeedback-assisted pelvic floor muscle training on quality of life and episode of voiding in women with overactive bladder

Public title

The comparison between Percutaneous posterior tibial nerve stimulation and Biofeedback-assisted pelvic floor muscle training

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

married women 18 to 45 years with the symptoms of overactive bladder

Exclusion criteria:

stress incontinence using pace maker
Cognitive impairment
diseases Superficial or deep infection at the electrode site
Uncontrolled urinary tract infection
Neurological diseases and urinary congestion
bladder stone
Uterine prolapse above second degree according to the POP-Q system
Pregnancy or suspected pregnancy or planning for it and cesarean delivery
Uncontrolled diabetes mellitus
History of surgeries to control incontinence and botulinum toxin injection
Pelvic tumors and history of radiotherapy

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After a complete explanation of the treatment methods and obtaining informed consent to participate in the study, patients are randomly divided into two groups by closed envelopes. In this simple randomization method, 60 envelopes are considered. 30 of them are biofeedback and the other 30 are PTNS . Then by merging the cards together and shuffling them, a card is taken out and its allocation is recorded. This merging and shuffling of the cards is then repeated for each patient.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University of Medical Science

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Babol University of Medical Sciences, Ganj Afroz Str., Babol, Mazandaran

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Approval date

2021-06-14, 1400/03/24

Ethics committee reference number

IR.MUBABOL.REC.1400.163

Health conditions studied**1****Description of health condition studied**

Overactive Bladder

ICD-10 code

N32.81

ICD-10 code description

N32.81 is a billable/specific ICD-10-CM code that can be used to indicate a diagnosis for reimbursement purposes.

Primary outcomes**1****Description**

Number of daily urination

Timepoint

Beginning of the study (before the start of the intervention) - End of the twelfth session - One month after the last session

Method of measurement

Daily Urine Record

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before the intervention - end of the twelfth session - one month after the last session

Method of measurement

Quality of Life Questionnaire in Patients with Incontinence (ICIQ-LUTSqol)

2

Description

Frequent urinary incontinence

Timepoint

Before the intervention - end of the twelfth session - one month after the last session

Method of measurement

Short form of urinary incontinence (ICIQ-UI SF)

3

Description

Number of nocturnal urination

Timepoint

Before the intervention - end of the twelfth session - one month after the last session

Method of measurement

Daily urine record

4

Description

number of urinary urgency feeling

Timepoint

Before the intervention - end of the twelfth session - one month after the last session

Method of measurement

Daily urine record

Intervention groups

1

Description

intervention group 1: Receiving electrical stimulation of posterior tibial nerve, 12 sessions (three sessions per week), by portable dual channel TENS devise

Category

Treatment - Other

2

Description

intervention group 2: pelvic floor muscles training with biofeedback, 12 sessions (three sessions per week), by vaginal electrode and MyoTrac Infiniti biofeedback device

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pelvic floor Clinic of Rouhani Hospital

Full name of responsible person

Shahnaz Barat

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Rouhani Hospital, Ganj Afrooz St., Babol, Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences
Full name of responsible person
Maryam Ebrahimi
Position
Master student of Physiotherapy
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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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments