# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 Per cutaneous 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**

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**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**

**Country**

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
**Street address**
Babol University of Medical Sciences, Ganj Afrooz Str., Babol, Mazandaran
**City**
Babol
**Province**
Mazandaran
**Postal code**
۴۷۱۷۶-۴۷۷۴۵
**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**
Babol University of Medical Sciences
**Full name of responsible person**
Ghadamali Talebi
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**Phone**
+98 11 3219 9592
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info@mubabol.ac.ir
**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

**Latest degree**
Bachelor

**Other areas of specialty/work**
Physiotherapy

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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**
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**