Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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

_

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)

Phone

+98 11 3219 4641

Email address

maryamebrahimi.pt89@gmail.com

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
Street address
Rouhani Hospital, Ganj Afrooz St., Babol, Mazandaran
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 3223 8301
Email
info@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Ghadamali Talebi
Street address
Babol University of Medical Science, Ganj Afrooz St., Babol, Mazandaran
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 3219 9592
Email
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

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴

Phone
+98 11 3219 9592

Email
maryamebrahimi.pt89@gmail.com

Person responsible for scientific 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

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 9592

Email
maryamebrahimi.pt89@gmail.com

Person responsible for updating data

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

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 9592

Email
maryamebrahimi.pt89@gmail.com

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