Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Efficacy of the percutaneous tibial nerve stimulation in the treatment of OABS (Over Active Bladder Syndrome) in both technique :unilateral and bilateral nerve stimulating

Protocol summary

Study aim

Efficacy of the percutaneous tibial nerve stimulation in the treatment of OABS (Over Active Bladder Syndrome) in both technique :unilateral and bilateral nerve stimulating

Design

Using the online site sealedenvelop.com (the site for sequencing block randomization) The four blocks are randomly assigned to patients in two groups: A: The patient receives only one electrode, and B: The patient receives both electrodes (standard treatment). The order in which the patients are placed to receive the electrode is provided to the technician. The study is Double blind. (Patient and surgeon) 32 patients referred to Sinai Hospital (with ethical consent) are studied. The study is an intervention, phase 3, parallel and therapeutic.

Settings and conduct

This clinical trial will be performed on 32 patients at Sina Hospital. Double blind(Patient and surgeon) Technician (importer of patients in each group based on random blocks) Random blocks, four blocks randomly from patients A: an electrode B: two electrodes 8 quadruple blocks are made which are placed in separate envelopes. Randomized blocks are given to a technician. After the patient enters, the technician performs the intervention by opening each envelope regarding the intervention method (A or B) for the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 50 years Patients with OAB Exclusion criteria:People with neurological disease People with any cancer History of chemotherapy or radiotherapy History of pelvic surgery includes history of urological surgery

Intervention groups

First Intervention Group: One-way PTNS Second Intervention Group:Two-way PTNS (Standard treatment)

Main outcome variables

Urgent urinary incontinence

General information

Reason for update

Due to the low number of resistant PTNS patient samples, the number of samples was reduced to 32, 16 in each group.

Acronym

OABS (Over Active Bladder Syndrome)

IRCT registration information

IRCT registration number: **IRCT20190624043991N7**
Registration date: **2020-07-31, 1399/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**
Update count: **1**

Registration date

2020-07-31, 1399/05/10

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8560

Email address

mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of the percutaneous tibial nerve stimulation in the treatment of OABS (Over Active Bladder Syndrome) in both technique :unilateral and bilateral nerve stimulating

Public title
percutaneous tibial nerve stimulation in the treatment of Over Active Bladder Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 50 years Patients with OAB
Exclusion criteria:
People with neurological disease People with any cancer History of chemotherapy or radiotherapy History of pelvic surgery includes history of urological surgery
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study is a double-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined.According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team.Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician.The patient is placed in unilateral or bilateral nerve stimulating treatment group based on the randomly selected envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients who have given their consent to participate in the study and Therapist To perform the blinding process, envelopes related to the type of intervention are provided only to the technician. The physician is not informed of the type of intervention (bilateral or unilateral) (to avoid bias). In both methods of intervention, two electrodes are connected to the patient, but randomly, the electrode current is one-way or two-way. Therefore, the patient will not know the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee for Research in Tehran University of Medical Sciences
Street address
Room 604, Sixth Floor, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-03-11, 1398/12/21
Ethics committee reference number
IR.TUMS.VCR.REC.1398.1041

Health conditions studied

1

Description of health condition studied
Over Active Bladder Syndrome
ICD-10 code
N32.81
ICD-10 code description
Overactive bladder

Primary outcomes

1

Description
urgent incontinence
Timepoint
At the end of the first day after treatment, at the end of the first week, and at the end of the first month after treatment
Method of measurement

Daily bladder function report

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One-way PTNS. Using the delicate needle of the electrode attached to the upper thigh stimulator of patients with OAB, we access the tibial nerve. In a one-way PTNS, an electrode is installed on both lower limbs of the patient, but current flows through one of the electrodes.
Category
Treatment - Other

2

Description
Intervention group: Two-way PTNS. Using the delicate needle of the electrode attached to the upper thigh stimulator of patients with OAB, we access the tibial nerve. In a two-way PTNS, the electrode is mounted on both lower limbs of the patient and passes through both current electrodes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr Mohammad Kazem Aghamir
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Hassan Abad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Tehran, Iran
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Province
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Email
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Web page address
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Akram Mirzaei
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akram Mirzaei
Position
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Latest degree
Ph.D.
Other areas of specialty/work
Molecular Medicine
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mirzaee.scholar@gmail.com
Web page address
https://URC@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
demographic information anonymously
When the data will become available and for how long
one year after publication
To whom data/document is available
Researchers working in academia, physicians, surgeons and hospitals
Under which criteria data/document could be used
Re-information for the purpose of clarification Using data by referring to the article's original Get permission from the author of the article and the presenter
From where data/document is obtainable
Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560
What processes are involved for a request to access data/document
After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.
Comments
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