

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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+98 21 6634 8560

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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 balanced 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 sealed envelope 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

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Tehran, Iran

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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

Molecular Medicine

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Person responsible for updating data

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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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