Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The effect of local vibration on restless legs syndrome

Protocol summary

Study aim
The main goal of the project: -Investigating the effect of topical vibration on reducing symptoms in people suffering from restless legs syndrome

Design
A parallel-group, single-blind, randomized, phase 2 clinical trial on 36 patients. The randomization method is done in the form of restricted randomization and random allocation rule.

Settings and conduct
The studied population is the patients referring to the Department of Physical Medicine and Rehabilitation of Firoozgar Hospital. They are divided into two groups for local vibration and gabapentin treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age 18 to 60 years - Having symptoms for at least 15 days during the 30 days leading up to the start of the intervention - Patients with at least moderate symptoms Exclusion criteria: - Pregnancy or breastfeeding - Existence of a pacemaker or ICD - Existence of active malignancy - Evidence of radiculopathy or neuropathy - Chronic disease - Psychological disorders

Intervention groups
The patients are divided into two groups for local vibration group and treatment with gabapentin. The first group are treated with a vibrator every night before going to sleep on the calve muscles for one month, and in the second group they are also treated with 300 mg of gabapentin daily.

Main outcome variables
-Severity of the patients' symptoms -Examine sleep quality parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190306042945N4**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

Registrant information

Name
Bijan Forogh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of local vibration on restless legs syndrome

Public title
The effect of local vibration on restless legs syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Having symptoms for at least 15 days during the 30 days leading up to the start of the intervention Satisfaction with the completion of the project Having 4 criterias Patients with at least moderate symptoms Stop taking any medication for the treatment of restless leg syndrome at least two weeks before

Exclusion criteria:

Pregnancy or breastfeeding Reluctance to treat local vibration The presence of a pacemaker or ICD Existence of active malignancy Existence of fracture, open wound, abscess, cellulitis or infection at the place of vibration CKD (GFR<60) Iron deficiency anemia (ferritin less than 20) Vitamin deficiency (Vit D level < 30) Deep vein thrombosis (DVT) Evidence of radicular pain, radiculopathy or neuropathy (clinical or paraclinical evidence) Background diseases such as diabetes, thyroid diseases, Parkinson's, rheumatological diseases and... The history of the company in research projects for the treatment of restless legs syndrome at least during the last month. History of drug or alcohol abuse Psychological disorders (such as depression, anxiety disorder, etc.) or any cognitive disorder Movement disorders (tremor, dystonia, etc.)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly divided into two groups for local vibration intervention (first group) and gabapentin treatment (second group). The randomization method is done in the form of restricted randomization and random allocation rule. In this method, numbers 1 and 2 (representative of the first and second groups) are written on papers of the same size and design and placed inside the envelope. And after moving the envelopes, the sufferers are asked to choose one of them randomly.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding method: After collecting the data, their analysis is done by another person (other than the main researcher) who does not know how to group the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Iran University of Medical Sciences, Central Headquarters Building, Research and Technology Vice-Chancellor, next to Milad tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-10-29, 1401/08/07

Ethics committee reference number

IR.IUMS.FMD.REC.1401.386

Health conditions studied

1

Description of health condition studied

Restless leg syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Severity of symptoms and restlessness of the legs

Timepoint

Before the beginning, after the last session and one month after the end of the intervention

Method of measurement

International Restless Leg Syndrome Study Group Rating Scale (IRLSRS)

Secondary outcomes

1

Description

Sleep quality

Timepoint

Before the beginning, after the last session and one month after the end of the intervention

Method of measurement

Standardized questionnaire Pittsburg in Farsi

Intervention groups

1

Description
Intervention group: under treatment with local vibration with a vibrator device with the trade name VBA (which is delivered to them) with low voltage (3 volts) and frequency in the range of 80-120 Hz for 35 minutes every night before going to bed. On the calf muscles and also during attacks of restlessness and unpleasant feelings for a period of one month.
Category
Treatment - Devices

2

Description
Intervention group: under treatment with 300 mg gabapentin daily (at night one hour before sleep) for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firouzgar Hospital
Full name of responsible person
Hamid Ansari
Street address
Firouzgar Hospital, Beh Afarin St., Valiasr Square
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Sponsors / Funding sources

1

Sponsor
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Hamid Ansari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data: All data can be shared after de-identifying individuals. Study protocol: The entire protocol can be shared after de-identifying people. Statistical analysis map: The whole map can be shared after de-identifying people. Informed Consent Form: Can be shared after de-identifying individuals. Clinical Study Report: The entire report can be shared after de-identifying individuals. Codes used in the analysis: All codes can be shared after de-identifying people. Data classification system: It can be shared after de-identifying people.
When the data will become available and for how long
The access period starts from 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
In case of research on a similar topic, he/she can use the data of this research.
From where data/document is obtainable
1- Email: hamida2091@gmail.com 2- Postal address: Firouzgar Hospital, Beh Afarin St., Valiasr Square, Tehran
What processes are involved for a request to access data/document
After correspondence via e-mail or postal address, it is possible to receive data and documents within a period of two months at the discretion of the researcher.
Comments