Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The effect of Transcutaneous Electrical Nerve (TENS) on the restless leg syndrome (RLS) In patients with this complaint

Protocol summary

Study aim
Evaluation of the effect of TENS on severity of restless legs syndrome (RLS) in patients with this complaint

Design
The present study is a single blind randomized clinical trial. Patients who meet the eligibility criteria will be asked to complete a questionnaire. People with a score above 4 will be randomly divided into intervention and control groups (40 patients in each group).

Settings and conduct
The present study will be performed in the office of Internal medicine specialist. Both groups receive their usual treatment, which will be prescribed by an Internal medicine specialist. Before connecting them to the TENS device and after separating the device, RLS questionnaires will be completed. To match the working process, the PM70 2-channel TENS device manufactured by Iran will be used.

Participants/Inclusion and exclusion criteria
People with suspected RLS who have diagnostic criteria for restless legs syndrome will receive an IRLSS questionnaire. Those with a score above 4 will be selected as the sample if they are eligible for the study. If they have a history of mental illness, vascular disease, neuromuscular disorders, experiencing a crisis for the past 3 months, taking antispasmodics, anticonvulsants, antidepressants, sedatives and herbal remedies and other non-pharmacological treatments during the past two weeks, will be excluded from the study.

Intervention groups
In this study, the TENS electric current is used at a frequency of 100 Hz, twice a week (Twice in total), and each time, for 20 minutes. Due to the location of the complication, the electrodes are attached to the extremities (legs) and their efficacy is evaluated according to the patient's condition. In the intervention group, the TENS device with HZ100 frequency will be used.

Main outcome variables
Severity of restless leg syndrom

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191217045764N1**
Registration date: **2020-01-01, 1398/10/11**
Registration timing: **prospective**

Last update: **2020-01-01, 1398/10/11**
Update count: **0**

Registration date
2020-01-01, 1398/10/11

Registrant information

Name
Ali Abedi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-18, 1398/11/29

Expected recruitment end date
2020-06-18, 1399/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Transcutaneous Electrical Nerve (TENS) on the restless leg syndrome (RLS) In patients with this complaint

Public title
The effect of Transcutaneous Electrical Nerve (TENS) on the restless leg syndrome (RLS)

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People over 35 years old Restless leg syndrome based on patient self-report Restless leg syndrome based on a doctor's diagnosis And in the final step, score higher than 4 based on the standard questionnaire

Exclusion criteria:
There is a history of psychiatric illness except restless leg syndrome Vascular diseases except restless leg syndrome according to physician Neuromuscular Disorders (Technique Problem) Experience the crisis over the past 3 months Patient's unwillingness to cooperate in design Severe stress to the individual or family over the past two weeks(death of a family member, ...) Intensify of RLS Use of antispasmodics over the past two weeks Use of anticonvulsants in the past two weeks Use of antidepressants over the past two weeks Use of sedatives over the past two weeks Using herbal remedies or any non-pharmacological treatments for treating restless legs syndrome over the past two weeks

Age
From **35 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Permissive blocks will be used for random allocation of patients.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will be unaware of being in the control and intervention groups. In order to not exchange information between the patients in the two groups; patients will be considered for interview and training in the separate room. Patients are reminded to not exchange information with other patients during the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Esfarayen University of Medical Sciences

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No. 70, Imam Reza Alley12 , Imam Reza Ave

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Approval date
2019-12-17, 1398/09/26

Ethics committee reference number
IR.ESFARAYENUMS.REC.1398.009

Health conditions studied

1

Description of health condition studied
Restless Legs Syndrome

ICD-10 code
G25.81

ICD-10 code description
Restless legs syndrome

Primary outcomes

1

Description
Severity of restless leg syndrome

Timepoint
At the beginning of the study (before the intervention). Immediately after intervention on two occasions, twice a week (Twice in total), in each time an intervention.

Method of measurement
Using the International Restless Legs Syndrome Study Group (IRLSS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In this study, the TENS electric current is used at a

frequency of 100 Hz, twice a week (Twice in total), and each time an intervention, for 20 minutes. Due to the location of the complication, the electrodes are attached to the extremities (legs). The efficacy of TENS is evaluated according to the patient's condition. In the intervention group, the TENS device with HZ100 frequency will be used.

Category

Treatment - Devices

2

Description

Control group: in this group placebo TENS will be used. The leads connect to the lower extremities, but the device is off.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Internal Medicine Doctor's Office

Full name of responsible person
Dr. Mohammad Ghasem Tabey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Esfarayen 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
Sabzevar University of Medical Sciences

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Position
Instructor

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The required data will appear in the article.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available