

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 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 transcutaneous electrical nerve stimulation (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 (15 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 RLS 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, 3 times in three consecutive days, 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: **IRCT20191217045764N2**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

Ali Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

abedia1371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-24, 1398/12/05

Expected recruitment end date

2021-04-25, 1400/02/05

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 in the final step, score higher than 4 based on the standard questionnaire

Exclusion criteria:

History of neurological disease other than Restless Legs Syndrome Presence of vascular diseases other than restless legs syndrome according to the doctor's opinion 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, ...) Intensification 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 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Permissive blocks will be used for random allocation of patients. So we have 5 blocks with two repetitions in each block (BABA, BAAB, ABAB, AAB, ABBA) and we selected 10 numbers from the table of random numbers, so that if the numbers 1 and 0 were selected, the first block, the number 3 and 2, the second block, the number 5 and 4, the third block, 6 and 7 Blocks, the fourth block, 8 and 9, the fifth block, were selected and the final allocation of samples was calculated from the sequence of these blocks.

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

Not 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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esfarayen

Province

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Postal code

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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

Before the start of the first stage intervention, before the start of the second stage intervention, before the start of the third stage intervention, the day after the third stage intervention.

Method of measurement

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the transcutaneous electrical nerve stimulation (TENS) electric current is used at a frequency of 100 Hz, three times in three consecutive days, 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

Esfarayen University of Medical Sciences

Full name of responsible person

Dr. Ali Asghar Neshat

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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

Esfarayen University of Medical Sciences

Full name of responsible person

Ali Abedi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

Person responsible for updating data**Contact****Name of organization / entity**

Esfarayen University of Medical Sciences

Full name of responsible person

Ali Abedi

Position

Instructor

Latest degree

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