# 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**
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Iran (Islamic Republic of)
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**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, AABB, 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 forth 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

**Street address**
No. 70, Imam Reza Alley12 , Imam Reza Ave

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esfarayen

**Province**
North Khorasan

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9661876981

**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**
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## Sponsors / Funding sources

### 1

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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**
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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