

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of Transcutaneous electrical nerve stimulation on the severity of restless legs syndrome in hemodialysis patients referred to the dialysis ward of Sabzevar Vasei Hospital and Imam Khomeini Hospital in Esfarayen

#### Protocol summary

##### Study aim

Determining the effect of transcutaneous electrical nerve stimulation on the severity of restless legs syndrome in hemodialysis patients. This study is a non-invasive, low-cost, uncomplicated and available method.

##### Design

In this study, 60 patients with restless legs syndrome and inclusion criteria who are referred to hemodialysis centers are selected. Participants are divided into two groups of intervention and control (sham) through permutation block.

##### Settings and conduct

This study will be performed on 30 patients in the intervention group and 30 patients in the control group (sham) who met the inclusion criteria and will be divided into permutation blocks. Patients in both groups will be blinded in this study for 3 times. 20 minutes for test and control patients (sham) with a specific frequency electrical nerve stimulation device will be examined. The status of restless legs syndrome in hemodialysis patients with international RLS will be recorded before and after the intervention in both groups. Results of 2 groups using Armons Will be statistically analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having restless legs syndrome based on the patient's self-declaration and the diagnosis of the treating physician, and in the last stage obtaining a score higher than 4 2. No history of neurological disease other than restless legs syndrome 3. Lack of experience of crisis during the last 3 months Exclusion criteria: 1. Severe stress on a person or family

##### Intervention groups

Intervention group: The effectiveness of transcutaneous electrical nerve stimulation with a frequency of 100 Hz on 30 hemodialysis patients with restless legs syndrome Control group (sham): the effectiveness of electrical

stimulation of the superficial nerve with a frequency of 20 Hz on 30 hemodialysis patients with restless leg syndrome

##### Main outcome variables

Restless leg syndrome

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220601055047N1**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

##### Registration date

2022-09-03, 1401/06/12

##### Registrant information

##### Name

abolfazal kalmishi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3722 6852

##### Email address

kalmishi.a@esfrums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

**Expected recruitment end date**

2022-12-22, 1401/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Transcutaneous electrical nerve stimulation on the severity of restless legs syndrome in hemodialysis patients referred to the dialysis ward of Sabzevar Vasei Hospital and Imam Khomeini Hospital in Esfarayen

**Public title**

The effect of Transcutaneous electrical nerve stimulation on restless legs syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Hemodialysis patients aged 18-75 years and older suffering from restless leg syndrome based on the self-report of the hemodialysis patient no history of neurological and mental illness except restless leg syndrome Absence of vascular diseases except restless leg syndrome absence of neuromuscular disorders, absence of crisis experience during the last 3 months

**Exclusion criteria:**

The patient's unwillingness to cooperate Antispasmodic use in the past two weeks Anticonvulsant use within the past two weeks Use of sedatives in the past two weeks Use of antidepressants in the past two weeks Use of herbal medicines during the last two weeks

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sequence of random allocation and the list of blocks, by the statistical consultant and to Software help will be available. website <https://www.sealedenvelope.com> is a useful site for production The random sequence for randomization is block type. This site It is designed in such a way that there is a limit in the number of groups There is no random assignment. From block method to volume 4 to create A random allocation sequence is used. According to the total number of samples The requirement for the study is 60 patients. 30 patients in the intervention group A and 30 patients are in group B. There are 15 quadruple blocks including two Group A and B are randomly designed through the software, for

example Continue on..... (ABAB), (BBAB), (AABB), (ABBA), (BAAB) Based on the sample size, 60 envelopes 30 envelopes including paper containing A and 30). An envelope containing B is prepared. Based on the list of blocks A randomly prepared quadruple, a trained person outside the research team, He is responsible for randomly assigning patients, after the arrival of each Patient and hospitalized in the special ward, according to 15 blocks of four prepared in The first stage of each patient randomly in intervention group A and group B The samples will be placed and the sample process will be done sequentially Sampling will be done, the code of each patient to his family member as well Will allocate data. People in the order of their entry into the study and form Randomly assigned to the desired group through randomized blocks Finds. For example, according to the ABAB block, each patient after entering the study, entered into the intervention, sham, intervention and sham groups, respectively will be This process continues until the last block is selected.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, patients in each intervention and control group (sham) will be considered as a separate room for not exchanging information with patients referred for interview and training, and patients will be reminded not to 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**

Research Ethics Committee of Sabzevar University of Medical Sciences

**Street address**

Sabzevar, Tawheed Shahr Blvd., above the Martyrs' Tomb, University Campus Building, Educational Assistant

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Approval date**

2022-07-13, 1401/04/22

**Ethics committee reference number**

IR.MEDSAB.REC.1401.013

## Health conditions studied

1

### Description of health condition studied

Severity of restless leg syndrome in hemodialysis patients

### ICD-10 code

N18.5

### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

1

### Description

Severity of restless legs syndrome

### Timepoint

3 shifts of 20 minutes

### Method of measurement

Restless Leg Syndrome International Questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In this study, after confirming restless leg syndrome, TENS electric current with a frequency of 100 Hz will be performed for the patients of the test group for 3 times and for 20 minutes in each stage.

### Category

Treatment - Other

2

### Description

Control group: In this study, after confirming restless legs syndrome, TENS electric current with a frequency of 20 Hz will be performed for the patients of the test group for 3 times and for 20 minutes in each stage.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Vasi Sabzevar Hospital - Imam Khomeini (RA) Esfrain Hospital

#### Full name of responsible person

Abolfazal Kalmishi

#### Street address

Sabzevar - Tawhid Shahr Blvd., Mohammad Vasei-

Esfrain Hospital, Imam Reza St., Abu Ali Sina Square, Imam Khomeini Hospital (RA)

### City

Sabzevar - Esfrain

### Province

Razavi Khorasan

### Postal code

9617913114

### Phone

+98 58 3722 6004

### Email

a.kalmish2020@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Sabzevar University of Medical Sciences

#### Full name of responsible person

Mohammad Hossein Saqi

#### Street address

Sabzevar- Tawheed Shahr Boulevard above the memorial of the unknown martyrs, University of Medical Sciences campus, Vice-Chancellor for Research and Technology

#### City

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#### Province

Razavi Khorasan

#### Postal code

9617913112

#### Phone

+98 51 4401 8101

#### Email

vc.Research@medsab.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Sabzevar 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

#### Full name of responsible person

Abolfazal Kalmishi

**Position**

Masters

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Esfrain, Nawab St., Shahid Moradi Alley

**City**

Esfrain

**Province**

North Khorasan

**Postal code**

9661665596

**Phone**

+98 58 3722 6852

**Email**

a.kalmish2020@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Abolfazal kalmishi

**Position**

Masters

**Latest degree**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

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abolfazal kalmishi

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be 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**

Part of the data, such as the information related to the main outcome or the like, will be shared.

**When the data will become available and for how long**

The access period begins 4 months after the results are published.

**To whom data/document is available**

Researchers working in academic institutions and hospitals

**Under which criteria data/document could be used**

1- For the use of other patients who have this restless legs syndrome, except hemodialysis patients 2- To provide new research work with more patients and new variables

**From where data/document is obtainable**

Sabzevar Faculty of Medical Sciences - University Central Library Contact number: 05144018300 Esfrain Faculty of Medical Sciences - Imam Khomeini Hospital (RA) - Abolfazl Kalmishi09232709619 : contact number

**What processes are involved for a request to access data/document**

Go to the library of Sabzevar University of Medical Sciences and refer to the librarian and receive the electronic pdf of the thesis Also, contact the author of the thesis and send the thesis to the target person

**Comments**