Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The effect ofTranscutaneous 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 oftranscutaneous 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

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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 ofTranscutaneous 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 ofTranscutaneous electrical nerve stimulation onrestless 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
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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
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Sponsors / Funding sources

1

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Sabzevar University of Medical Sciences
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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
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
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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