Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effect of Transcutaneous Electrical Acupoint Stimulation and Infrared on the Severity of the restless leg Syndrome

Protocol summary

Study aim
Comparison of the effect of acupuncture points and infrared light on the severity of restless legs syndrome
Design
This clinical trial design has a control and intervention group, with parallel, double-blind and simple random groups.
Settings and conduct
This clinical trial study will be conducted on patients with this syndrome in 8 sessions of Transcutaneous Electrical Acupoint Stimulation and infrared light points after using restless legs syndrome universal questionnaire. Participants and statistical analysts will perform.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent to participate in the study Having restless legs syndrome Age range between 18 and 65 years Not being cancer Not receiving pharmacological and non-pharmacological treatment to relieve restless leg syndrome Not having pacemaker Exclusion criteria: Failure to attend more than 3 sessions Using Restless Foot Syndrome Soothing Medications Migration Death
Intervention groups
Transcutaneous Electrical Acupoint Stimulation group Infrared group
Main outcome variables
Severity of restless leg syndrome

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190925044884N1**
Registration date: **2019-12-24, 1398/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-24, 1398/10/03**
Update count: **0**
Registration date
2019-12-24, 1398/10/03

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-23, 1398/08/01
Expected recruitment end date
2020-01-21, 1398/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Transcutaneous Electrical Acupoint Stimulation and Infrared on the Severity of the restless leg Syndrome

Public title
Comparison of the Effect of Transcutaneous Electrical Acupoint Stimulation and Infrared on the Severity of the restless leg Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent to participate in the study Having restless legs syndrome Age range between 18 and 65 years Not being cancer Not receiving pharmacological and non-pharmacological treatment to relieve restless leg syndrome Not having pacemaker
Exclusion criteria:
Failure to attend more than 3 sessions Using Restless Foot Syndrome Soothing Medications Migration Death

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple randomization method will be used. The random number table will be used to select the samples and place them in the intervention and control modes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in this study will not know which of the intervention and control groups they belong to. The data analyzer also does not know which data belongs to which group.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Branch of researchs and industry,Kermanshah University Of Medical Sciences, Shahid Beheshti Blvd, Kermanshah, Iran
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Postal code
6715847141
Approval date
2019-09-17, 1398/06/26
Ethics committee reference number
IR.KUMS.REC.1398.686

Health conditions studied

1

Description of health condition studied
Restless leg syndrome
ICD-10 code
G25.81
ICD-10 code description
Restless legs syndrome

Primary outcomes

1

Description
In this study, we compared the effect of acupuncture points and infrared light on the severity of restless legs syndrome using the restless legs syndrome universal questionnaire whose score is below 4.
Timepoint
In this study, we compared the efficacy of acupuncture points and infrared light on the severity of restless leg syndrome, the first measurement with a pre-test and the second with a post-test, and the third measurement to determine whether the method was effective. Whether or not treatment will continue, one month after the end of treatment, re-treatment will be perform
Method of measurement
Restless Foot Syndrome World Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Transcutaneous Electrical Acupoint Stimulation.In the electrical stimulation intervention group, skin stimulation was performed with AcuHealth (Australian Made) at specified locations.Electrical stimulation of the specimens was performed for each sample for 4 consecutive weeks, 3 times a week, and every 5 minutes.
Category
Treatment - Devices

2

Description
Intervention group: Infrared.In the infrared intervention group, infrared light therapy sessions are conducted in

two sessions, with each individual in the intervention group being treated three times a week for one month. The BioBeam940 (Israel-made) portable, FDA-approved, portable, hand-held device is used to conduct infrared light therapy sessions. In this regard, the 2 nm wavelength in the NIR range, with a power of 1 mW / cm2, a frequency of 2 Hz, a maximum focusing power of 2 mW, and a 2 degree radiation angle are applied to each acupuncture point of each foot as well as the entire plantar surface of each. The foot will be exposed to infrared light It should be noted that the energy transfer to each acupuncture point is two minutes in order to transmit energy to the foot from the method used in the bath so that the infrared probe in The whole plantar surface will move about for 5 minutes, so each person will have to walk 5 minutes in total. Session receives infrared light.

Category

Treatment - Devices

3

Description

Control group: Intervention group: Transcutaneous Electrical Acupoint Stimulation.While the sessions in the control group will be administered in the form of dummy treatment, the researcher only pretends that he is undergoing electrical stimulation therapy in the control group, but in fact, the acupuncture points of these individuals are not stimulated.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences Research Center for Sleep Disorders

Full name of responsible person

Behnam Khaledi Paveh

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Farabi Hospital, Dollat Abad, Kermanshah, Iran

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Sponsors / Funding sources

1

Sponsor

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Nazarian Pirdosti

Position

nursing student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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