Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The survey of the impact of infrared light therapy based on acupuncture points on the severity of restless leg syndrome in patients undergoing hemodialysis

Protocol summary

Summary

The aim of the study was to determine the impact of infrared light therapy based on acupuncture points on the severity of restless leg syndrome in the hemodialysis patients. The design of this study is a randomized clinical trial. The inclusion criteria: informed consent for participation in the study; suffering from restless leg syndrome and the age range of 18 to 65 years. The exclusion criteria: failure to take part in the light therapy sessions in more than three sessions; recent use of restless leg syndrome drugs. The research sample size consists of 60 patients undergoing hemodialysis who are suffering from restless leg syndrome (intervention group 30, control group 30) and they are undergoing hemodialysis in Imam Reza hospital in Kermanshah city in 2017. The intervention in this study is using the infrared light on the acupuncture points for two minutes and during 12 sessions (three times a week). There is no intervention in the control group. After the intervention sessions, the restless leg syndrome is measured using the standard questionnaire of the restless leg syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112727779N3**
Registration date: **2017-09-16, 1396/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-16, 1396/06/25

Registrant information

Name

Mohammad Mehdi Mohammadi

Name of organization / entity

Kermanshah University of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 83 3836 1129

Email address

mm.mohammadi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of the impact of infrared light therapy based on acupuncture points on the severity of restless leg syndrome in patients undergoing hemodialysis

Public title

The impact of infrared light therapy in acupuncture points on the severity of restless leg syndrome in patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria: Informed consent for participation

in the study; suffering from restless leg syndrome; the age range of 18 to 65 years. Exclusion criteria: Unwillingness to continue participating in the study; failure to take part in the light therapy sessions in more than three sessions; recent use of restless leg syndrome drugs; kidney transplant; immigration or death.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Using sealed envelope to randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Kermanshah, Shahid Beheshti street, Building No. 2

City
Kermanshah

Postal code

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
KUMS.REC.1396.191

Health conditions studied

1

Description of health condition studied
Restless leg syndrome

ICD-10 code
G25.8

ICD-10 code description
Other specified extrapyramidal and movement disorders

Primary outcomes

1

Description
The severity of restless leg syndrome

Timepoint
Before the intervention, two weeks after the intervention, four weeks after the intervention, two weeks after the end of the intervention

Method of measurement
The standard questionnaire of the restless leg syndrome

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: The intervention in this study is using the infrared light in the acupuncture points for two minutes and during 12 sessions (three times a week).

Category
Rehabilitation

2

Description
The control group: There is no intervention in the control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Mohammad Mehdi Mohammadi

Street address
Imam Reza hospital, Baghe abrisham

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person
Behrooz Hamzeh

Street address
Building No. 2, Shahid Beheshti street, Kermanshah

City
Kermanshah
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Mohammadi
Position
MSc in Nursing
Other areas of specialty/work
Street address
Building No. 2, Shahid Beheshti street, Kermanshah
City
Kermanshah
Postal code
Phone
+98 83 3836 1129
Fax
Email
mehdi20.mohamadi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Mohammadi
Position
MSc in nursing
Other areas of specialty/work
Street address
Building No. 2, Shahid Beheshti street, Kermanshah
City
Kermanshah
Postal code
Phone
+98 83 3836 1129
Fax
Email
mehdi20.mohamadi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Mohammadi
Position
MSc in nursing
Other areas of specialty/work
Street address
Building No. 2, Shahid Beheshti street, Kermanshah
City
Kermanshah
Postal code
Phone
+98 83 3836 1129
Fax
Email
mehdi20.mohamadi@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty