

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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