

# 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**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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## 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*