Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of auriculotherapy on sleep quality, fatigue and severity of restless leg syndrome in hemodialysis patients

Protocol summary

Study aim
Determining the effect of auriculotherapy on sleep quality, fatigue and severity of restless leg syndrome in hemodialysis patients

Design
A randomized, parallel group, controlled trial

Settings and conduct
This study was designed with the aim of "determining the effect of auriculotherapy on sleep quality, fatigue and severity of restless legs syndrome in patients undergoing hemodialysis" in hospitals affiliated to Kashan University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Under continuous hemodialysis treatment for more than six months Exclusion criteria: - Not completing the daily note sheet and not doing enough intervention - Death of the patient during the study - Unwillingness to continue research- Use of painkillers and painkillers during the study

Intervention groups
60 hemodialysis patients with restless leg syndrome were randomly divided into two control groups and an intervention group. The intervention group is subjected to auriculotherapy in certain points for six weeks.

Main outcome variables
Severity of restless legs syndrome ؛sleep quality؛ fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130721014086N17**
Registration date: **2023-01-31, 1401/11/11**
Registration timing: **prospective**

Last update: **2023-01-31, 1401/11/11**
Update count: **0**

Registration date
2023-01-31, 1401/11/11

Registrant information
Name
Mohammad Aghajani
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of auriculotherapy on sleep quality, fatigue and severity of restless leg syndrome in hemodialysis patients

Public title
The effect of auriculotherapy on sleep quality, fatigue and severity of restless leg syndrome in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-60 Suffering from restless leg syndrome with a score of more than 4 from the International Restless Leg Syndrome Questionnaire scoring 5 or higher from the Pittsburgh Questionnaire hemoglobin higher than 10 mg/dL no peripheral neuropathy based on the patient's clinical record no psychiatric disease based on the patient's clinical record full consciousness no known cognitive problems (dementia, Alzheimer's) based on the patient's clinical record
Exclusion criteria:
Disability to read and write Having vision and hearing problems that interfere with the intervention

Age
From **18 years** old to **60 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
Samples are made in blocks of four and six using Sealed Envelope Ltd software. 2017 available through www.sealedenvelope.com are assigned to two intervention and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the participants are placed in two intervention and control groups. Stickers with seed are attached in certain areas in the intervention group, and in neutral areas in the control group. The patients do not know about its function.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research Faculty of Medicine and Dentistry- Kashan University of Medical Science

Street address
Kashan, km 3, Qutb Ravandi

City
Kashan

Province
Isfehan

Postal code
88715973474

Approval date
2023-01-08, 1401/10/18

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1401.192

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
Severity of restless legs syndrome

Timepoint
At the beginning of the study, the sixth week and the tenth week

Method of measurement
International standard restless leg syndrome questionnaire

Secondary outcomes

1

Description
sleep quality

Timepoint
At the beginning of the study, the sixth week and the tenth week

Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
fatigue

Timepoint
At the beginning of the study, the sixth week and the tenth week

Method of measurement
Multidimensional fatigue assessment questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will be

subjected to auriculotherapy at certain points for six weeks. In the intervention group, pads are attached to the Shenmen, Zero, Thalamus, Subcortex and Sympathetic points, and the patient is told how to apply pressure, which should be done in the form of medium pressure with the thumb and forefinger, every other day and every time 3- 4 times for one to two minutes, it will be explained.

Category
Treatment - Other

2

Description
Control group: In the control group, only the seeds are glued at neutral points and no pressure is applied.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospitals of Kashan University of Medical Science

Full name of responsible person
Fatemeh Asgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Mohammad Aghajani

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available