

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

Country

Iran (Islamic Republic of)

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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
 Isfahan

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

Golamali Hamidi

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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

Contact

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Latest degree

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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