Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Auricular acupressure on Nausea and Vomiting, Restless leg syndrome, and Sleep quality of patients undergoing hemodialysis referred to Imam Khomeini Hospital of Jiroft

Protocol summary

Study aim

To determine the effect of Auricular acupressure on Nausea and Vomiting, Restless leg syndrome, and Sleep quality of patients undergoing hemodialysis referred to Imam Khomeini Hospital of Jiroft

Design

In this study is a clinical trial with two control (sham)and intervention groups, single-blinded and randomized, with 30 patients in each group, randomization was done using a simple method using spss27 software.

Settings and conduct

This study will be conducted in the hemodialysis department of Imam Khomeini Hospital in Jiroft. the study outcomes will be evaluated in three stages: before the start of the intervention, immediately after the end of the intervention (week 6), and 4 weeks after the end of the intervention (week 10) in two intervention and control (sham) groups.

Participants/Inclusion and exclusion criteria

Entry criteria include:Age between 18 and 60 years, undergoing regular hemodialysis 2 to 3 times a week, Having at least 6 months of hemodialysis experience. Exclusion criteria :Having a cognitive impairment,Taking sedatives and sleeping pills, Absence from more than one intervention session

Intervention groups

Intervention group: in Intervention group,ear acupressure will be performed for 6 weeks, every other day. After applying the seeds to one ear, patients will be instructed to press the desired points 4 times a day , 2 times in the morning and 2 times in the evening .Control group: In the sham(control) group, seedless adhesives will be used in non-specific locations behind the earlobe to maintain similar appearance. These adhesives will be similar in appearance to the intervention group but will have no specific therapeutic effect.Individuals in this group will be instructed not to apply any pressure to the adhesive site or take any specific action.

Main outcome variables

Auricular acupressure, Restless legs syndrom, Nausea and vomiting, Sleep quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N22**
Registration date: **2026-08-03, 1405/05/12**
Registration timing: **prospective**

Last update: **2026-08-03, 1405/05/12**
Update count: **0**

Registration date

2026-08-03, 1405/05/12

Registrant information

Name
Batoul Tirgari
Name of organization / entity
Kerman Medical University of Sciences
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-11, 1405/05/20

Expected recruitment end date

2026-11-11, 1405/08/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Auricular acupressure on Nausea and Vomiting, Restless leg syndrome, and Sleep quality of patients undergoing hemodialysis referred to Imam Khomeini Hospital of Jiroft

Public title
The effect of Auricular acupressure on Nausea and Vomiting, Restless leg syndrome, and Sleep quality of patients undergoing hemodialysis referred to Imam Khomeini Hospital of Jiroft
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 60 years Having chronic kidney failure and undergoing regular hemodialysis 2 to 3 times a week Having at least 6 months of hemodialysis experience Full alertness and ability to respond to questionnaires Having a score of at least 4 in terms of Restless legs syndrome severity based on the RLS screening questionnaire Having a score of at least 5 on the Pittsburg Sleep Quality questionnaire Hemoglobin above 10 g/dl
Exclusion criteria:
Having a cognitive impairment including Dementia or Alzhaeimer or sever psychiatric illness as reported by the patient or physician Having concurrent diseases including Cancer, Congestive Heart Failure, Connective Tissue disease or Blood diseases Having a wound, Infection, inflammation, or skin sensitivity in the ear area Simultaneous use of other similar methods such as Acupressure or Acupuncture during the study Use of Painkillers, including nonsteroidal anti-inflammatory drugs or opioids Taking sedatives and sleeping pills Absence from more than one intervention session
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method is used to assign people to two intervention and sham groups in such a way that a list of people is prepared and then these people are numbered and divided into two intervention and sham groups using SPSS software version 27. In this way, we want the software to randomly place 30 people in the intervention group and 30 people in the sham group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The intervention and collection of questionnaires and checklists are done by the researcher, and the data analyst is a person other than the researcher and does not know which data are related to the intervention group and which data are related to the sham group. The information related to the intervention and sham groups will be entered into SPSS software under the title of group 1 and group 2. The analyst will not know which of the groups 1 and 2 is the intervention and sham groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616910002
Approval date
2026-07-20, 1405/04/29
Ethics committee reference number
IR.KMU.REC.1405.180

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
Z49.01
ICD-10 code description
Encounter for fitting and adjustment of extracorporeal dialysis catheter

2

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

3

Description of health condition studied

Restless legs syndrom

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Nausea and Vomiting

Timepoint

The effect of auricular acupressure on Nausea and Vomiting in Hemodialysis patients was evaluated in three stages including before the intervention, immediately after the end of the intervention week 6, and 4 weeks after the end of the intervention week 10

Method of measurement

Rhodes Index of Nausea and Vomiting

2

Description

Restless Legs Syndrome

Timepoint

The effect of auricular acupressure on Restless Legs Syndrome in Hemodialysis patients was evaluated in three stages including before the intervention, immediately after the end of the intervention week 6, and 4 weeks after the end of the intervention week 10

Method of measurement

International Restless Legs Syndrome Scale

3

Description

Sleep Quality

Timepoint

The effect of auricular acupressure on Sleep Quality in Hemodialysis patients was evaluated in three stages including before the intervention, immediately after the end of the intervention week 6, and 4 weeks after the end of the intervention week 10

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in Intervention group,ear acupressure will be performed for 6 weeks, every other day. In this group , a trained and certified researcher , under the supervision a traditional medicine specialist, will identify the ear treatment points, disinfect the desired points with 70% alcohol, and apply vacaria seeds to the marked points of one ear of the patient using medical adhesive, applying unilaterally.To maintain the stability of the intervention, vacaria seeds of the same brand available on the market will be used. The points will include Shen Man, Zero, Thalamus, Subcortex, and Sympathetic points. After applying the seeds to one ear, patients will be instructed to press the desired points 4 times a day , 2 times in the morning and 2 times in the evening . There is a 5 minute interval between each pressing session. patients will massage each point with moderate pressure, equivalent to 5 to 7 out of 10, for 1 to 2 minutes or untill a feeling of warmth, numbness, or tingling occurs. between each massage session, and the next point will be followed by a 1 minute interval. the researcher will show the paticipants how to press the points correctly during the training. simultaneously with the hemodialysis sessions, every 2 to 3days, the old beads and adhesive will be removed from one ear and new beads will be attached to the opposite ear. In case of discomfort , skin sensitivity or intolerance caused by the acupressure adhesive or beads, the adhesives or beads will be removed and the intervention will be stopped for the patient.

Category

Other

2

Description

Control group: In the sham(control) group, seedless adhesives will be used in non-specific locations behind the earlobe to maintain similar appearance. These adhesives will be similar in appearance to the intervention group but will have no specific therapeutic effect.Individuals in this group will be instructed not to apply any pressure to the adhesive site or take any specific action. the adhesive replacement and visits for this group will be scheduled at the same time as the intervention group so that the conditions of the two groups remain the same in terms of attention and contact with the researcher. to ensure patient adherence to the intervention , the researcher will be present in the ward for 1-2 dialysis sessions per week to directly monitor bead placement and pressure technique. on non-dialysis days, patients will record bead pressure sessions in a diary and will be followed up by the researcher by telephone. the diary will be reviewed during dialysis sessions where the researcher is present.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hemodialysis Center Imam Khomeini Hospital of Jiroft of Jiroft

Full name of responsible person
Batool Tirgari

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Jiroft, Imam Khomeini Boulevard , Shafa Street

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Sponsors / Funding sources

1

Sponsor

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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?
Yes

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Batool Tirgari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh-Alavi Highway, Kerman

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available