# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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

**Country**
Iran (Islamic Republic of)

**Phone**
+98 34 3132 5207

**Email address**
b_tirgari@kmu.ac.ir

**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

**Street address**
Jiroft, Imam Khomeini Boulevard , Shafa Street

**City**
Jiroft

**Province**
Kerman

**Postal code**
7861933667

**Phone**
+98 913 195 0716

**Email**
b_tirgari@kmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
Batool Tirgari

**Street address**
Razi Nursing and Midwifery School, Medical Sciences Campus, Haft baghe alavi Road, Kerman

**City**
Kerman

**Province**
Kerman

**Postal code**
7616913555

**Phone**
+98 34 3132 5207

**Email**
B_tirgari@kmu.ac.ir

**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

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

**City**
Kerman

**Province**
Kerman

**Postal code**
7616913555

**Phone**
+98 34 3132 5207

**Email**
b_tirgari@kmu.ac.ir

## Person responsible for scientific 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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**Province**
Kerman

**Postal code**
7616913555

**Phone**
+98 34 3132 5207

**Email**
b_tirgari@kmu.ac.ir

## Person responsible for updating data

**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
**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh-Alavi Highway, Kerman
**City**
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**Province**
Kerman
**Postal code**
7616913555
**Phone**
+98 34 3132 5207
**Email**
b_tirgari@kmu.ac.ir

## 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