Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of auricular acupressure versus control group on the severity of fatigue and hemodynamics status of hemodialysis patients: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of auricular acupressure versus control group on the severity of fatigue and hemodynamics status of hemodialysis patients

Design
This is a Phase III randomized clinical trial without blinding with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct
This study will be conducted at the Beheshti Hospital in Hamadan city, involving 52 eligible hemodialysis patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. However, it should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years Being on hemodialysis for at least 3 months Feeling tired and bored Exclusion criteria: Wound or fracture of the auricle

Intervention groups
Intervention group 1: Routine care of dialysis patients, in addition to auricular acupressure, includes applying pressure of 3 to 4 kg using a pressure sticker of Vacaria plant in the area of the superior upper triangular fossa of the auricle for 3 minutes three times a day for a week. Intervention group 2: Routine care of dialysis patients, in addition to auricular acupressure, includes applying pressure of 3 to 4 kg using a pressure sticker of Vacaria plant in the area of the Shenmen of the auricle for 3 minutes three times a day for a week. Intervention group 3: Routine care of dialysis patients, in addition to auricular acupressure, includes applying pressure of 3 to 4 kg using a pressure sticker of Vacaria plant in the area of the heart of the auricle for 3 minutes three times a day for a week. Control group: Only routine care of dialysis patients

Main outcome variables
Primary outcome: Feeling tired, blood pressure, pulse count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N520**
Registration date: **2024-07-21, 1403/04/31**
Registration timing: **prospective**

Last update: **2024-07-21, 1403/04/31**
Update count: **0**

Registration date
2024-07-21, 1403/04/31

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-11, 1403/05/21

Expected recruitment end date
2024-10-12, 1403/07/21

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

Scientific title
Effect of auricular acupressure versus control group on the severity of fatigue and hemodynamics status of hemodialysis patients: a randomized clinical trial

Public title
Effect of auricular acupressure versus control group on the severity of fatigue and hemodynamics status of hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 65 years Being on hemodialysis for at least 3 months Feeling tired and bored
Exclusion criteria:
Wound or fracture of the auricle
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare four sheets, write A, B, C, and D letters on them. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2024-06-29, 1403/04/09
Ethics committee reference number
IR.UMSHA.REC.1403.201

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
I95.3
ICD-10 code description
Hypotension of hemodialysis

Primary outcomes

1

Description
Feeling tired
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Using Visual Analog Scale (VAS)

2

Description
Blood pressure
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Using a sphygmomanometer

3

Description
Pulse count
Timepoint
Before the intervention and one week after the intervention
Method of measurement
With clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Routine care of dialysis patients, in addition to auricular acupressure, includes applying pressure of 3 to 4 kg using a pressure sticker of Vacaria plant in the area of the superior upper triangular fossa of the auricle for 3 minutes three times a day for a week.
Category
Treatment - Other

2

Description
Intervention group 2: Routine care of dialysis patients, in addition to auricular acupressure, includes applying pressure of 3 to 4 kg using a pressure sticker of Vacaria plant in the area of the Shenmen of the auricle for 3 minutes three times a day for a week.
Category
Treatment - Other

3

Description
Intervention group 3: Routine care of dialysis patients, in addition to auricular acupressure, includes applying pressure of 3 to 4 kg using a pressure sticker of Vacaria plant in the area of the heart of the auricle for 3 minutes three times a day for a week.
Category
Treatment - Other

4

Description
Control group: Only routine care of dialysis patients
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan city
Full name of responsible person
Sepehr Mirzaei
Street address
Beheshti Hospital, Eram Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0283
Email
mirzaei3epehr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
Street address
Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Sepehr Mirzaei
Position
Nursing Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
mirzaei3epehr@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Khodayar Oshvandi
Position
PhD in Nursery
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
oshvandi2005@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.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