Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of auricular acupressure on pruritus, xerostomia, and fatigue of patients undergoing hemodialysis in Kerman University of Medical Sciences

Protocol summary

Study aim

Determining the effect of ear acupressure on pruritus, xerostomia and fatigue of hemodialysis patients in centers affiliated to Kerman University of Medical Sciences.

Design

En This study is a clinical trial with two groups, single blinded and randomized, with 41 patients in each group

Settings and conduct

This study will be conducted in the hemodialysis departments of the centers affiliated to Kerman University of Medical Sciences. In the intervention group, ear acupressure will be performed for 4 weeks. All types of itching, dry mouth and fatigue before the intervention and after the end of the intervention will be measured in two intervention and control groups.

Participants/Inclusion and exclusion criteria

Entry criteria include: age 18 to 75 years؛ Regular hemodialysis؛ Having at least 3 scores on the VAS visual analog scale for pruritus and experiencing xerostomia and fatigue in the last month. Exclusion criteria: presence of concomitant diseases including: cancer, congestive heart failure, connective tissue disease, hematological diseases and liver diseases؛ The presence of severe physical symptoms that clearly cause insomnia and fatigue, such as bone pain, sleep apnea, and restless legs؛ Fatigue due to severe anemia or malnutrition؛ ear infection؛ Allergy to Vaccaria seeds؛ Using medications that may cause xerostomia and itching.

Intervention groups

The intervention includes ear acupressure using Vacaria plant seeds in the specified points on the ear for the intervention group. The intervention lasts 4 weeks; According to the hemodialysis program, adhesives and beads will be replaced with new adhesives and beads every 2 to 3 days. For people in the control group, adhesives without Vacaria plant seeds are used in specified places and only under their usual daily care. are placed and no intervention will be done on them.

Main outcome variables

pruritus, xerostomia, and fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N14**
Registration date: **2022-12-12, 1401/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-12, 1401/09/21**
Update count: **0**

Registration date

2022-12-12, 1401/09/21

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5207

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-11-22, 1402/09/01

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

Scientific title
The effect of auricular acupressure on pruritus, xerostomia, and fatigue of patients undergoing hemodialysis in Kerman University of Medical Sciences

Public title
The effect of auricular acupressure on pruritus, xerostomia, and fatigue of patients undergoing hemodialysis in Kerman University of Medical Sciences
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient age between 18_75 years Regular hemodialysis Having at least 3 scores on the VAS visual analog scale for pruritus and experiencing xerostomia and fatigue in the last month
Exclusion criteria:
Existence of concomitant diseases including: cancer, congestive heart failure, connective tissue disease, hematological diseases and liver diseases. The presence of severe physical symptoms that clearly cause insomnia and fatigue, such as bone pain, sleep apnea, and restless legs. Fatigue due to severe anemia (hemoglobin <60 g/L) or malnutrition (serum albumin <30 g/L) ear infection Allergy to Vaccaria seeds Use of medications that may cause xerostomia (such as anticholinergics, tricyclic antidepressants, and beta blockers) Use of drugs that may cause pruritus (such as drugs and substances to which the patient is allergic, narcotic painkillers, antifungals).
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method is used to assign people to two control and intervention groups in such a way that a list of people is prepared and then these people are numbered and divided into two intervention and control groups using SPSS software version 26. In this way, we want the software to randomly place 41 people in the intervention group and 41 people in the control 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 control group. The information related to the intervention and control 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 control 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
7616913555
Approval date
2022-11-07, 1401/08/16
Ethics committee reference number
IR.KMU.REC.1401.316

Health conditions studied

1

Description of health condition studied
pruritus
ICD-10 code
L29.8
ICD-10 code description
Other pruritus

2

Description of health condition studied
xerostomia
ICD-10 code
K11.7
ICD-10 code description
Disturbances of salivary secretion

3

Description of health condition studied
fatigue
ICD-10 code
R53
ICD-10 code description
Malaise and fatigue

Primary outcomes

1

Description
pruritus
Timepoint
pruritus is measured before the intervention and at the end of the intervention.
Method of measurement
Visual analog scale

2

Description
xerostomia
Timepoint
xerostomia is measured before the intervention and at the end of the intervention.
Method of measurement
Summated Xerostomia Inventory

3

Description
fatigue
Timepoint
fatigue is measured before the intervention and at the end of the intervention.
Method of measurement
Fatigue Severity Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention includes ear acupressure using Vacaria plant seeds in the specified points on the ear for the intervention group. The intervention lasts 4 weeks; According to the hemodialysis program, adhesives and beads will be replaced with new adhesives and beads every 2 to 3 days.
Category
Other

2

Description
Control group: For people in the control group, adhesives without Vacaria plant seeds are used in specified places and only under their usual daily care. are placed and no intervention will be done on them.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Batool Tirgari
Street address
No. 1, End of Shafa Ave., Shafa Eduacational Hospital.
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7618751151
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Web page address
http://kmu.ac.ir/fa/snm

2

Recruitment center
Name of recruitment center
Saman Al-Hajj Charity Organization
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Javad Al-Aimah Specialized Medical Complex
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Razi Nursing and Midwifery School, Medical Sciences Campus, Haft baghe alavi Road, Kerman
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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
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
Batoul Tirgari
Position
Associate Professor
Latest degree
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Person responsible for updating data

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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