

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Vaccaria 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 Vaccaria 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

Email address

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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).

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget 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

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No. 1, End of Shafa Ave., Shafa Educational Hospital.

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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

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Full name of responsible person

Batol Tirgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Batoul Tirgari
Position
Associate Professor
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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