Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Auriculotherapy on the Severity of Constipation in Patients Undergoing Hemodialysis

Protocol summary

Study aim

Determining the effect of Auriculotherapy on the severity of constipation in patients undergoing hemodialysis

Design

This study is a single blind clinical trial performed in a time period of four months with two groups and three stages (before, immediately and one month after intervention) in four hemodialysis centers of Isfahan in Iran in 2018.Seventy patients are selected randomly and the subjects will be randomly assigned to two groups of 35 subjects.

Settings and conduct

Hemodialysis centers of Alzahra, Noor , Amin and Farabi Hospitals. The method of doing the study: the patients will be divided into two groups: intervention and control. In the intervention group, the intended points in the ears of the patients are stimulated by vaccaria seed. In the control group, adhesive, without vaccaria seed, will be located in the false points during a period of 10 sessions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Aged between 18 and 65 years old, having a history of constipation with the score of 1 and above according to the constipation assessment scale; undergoing dialysis three times a week and four hours each time; having at least six months of hemodialysis in advance Exclusion Criteria: Using anti-constipation drugs; skin disease; localized infections and lesion in the ear; having a history of advanced heart failure and stroke;the existence of electrical device in the body.

Intervention groups

Intervention group: For 10 sessions, vaccaria seeds will be located in the specific points in ears. Control group: Non-vaccaria seeds will be placed, like the intervention group, but on the false points in ears.

Main outcome variables

The severity of constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190319043091N1**
Registration date: **2019-05-19, 1398/02/29**
Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**
Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Houri Lahijanian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-24, 1397/02/04

Expected recruitment end date

2018-06-25, 1397/04/04

Actual recruitment start date

2018-05-10, 1397/02/20

Actual recruitment end date

2018-08-11, 1397/05/20

Trial completion date

2018-08-11, 1397/05/20

Scientific title

The Effect of Auriculotherapy on the Severity of Constipation in Patients Undergoing Hemodialysis

Public title
The Effect of Auriculotherapy on the Severity of Constipation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Having a history of constipation based on the scale of constipation scored 1 and more. Doing dialysis three times a week and four hours each time Having at least six months of hemodialysis in advance Having fix and active cases/records in the hemodialysis department of the intended center
Exclusion criteria:
The use of anti-constipation drugs Having skin disease, localized infections and lesion in the ear Having a history of advanced heart failure and stroke The use of electrical device in the body of the patient
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on a randomized allocation, 35 pockets include the term "control group" and 35 pockets the term "intervention group" and, then, the clients are asked to choose one pocket among these 70 ones. It should be noted that each pocket that is taken by individuals is returned to the packets so that all individuals can have equal chance in choosing the pockets.
Blinding (investigator's opinion)
Single blinded
Blinding description
Both ears of all subjects of each group were glued, while the subjects were not informed of the main and false points.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hezar Jereyb St., Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
81746734461
Approval date
2017-12-24, 1396/10/03
Ethics committee reference number
IR.MUI.REC.1396.3.618

Health conditions studied

1

Description of health condition studied
Constipation
ICD-10 code
K59.0
ICD-10 code description
Constipation

Primary outcomes

1

Description
Severity of constipation
Timepoint
The beginning of the study (before the start of the study) immediately after the intervention and one month after the end of the intervention
Method of measurement
The constipation assessment scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For 10 sessions with three days interval (30 days in total), vaccaria seeds will be located in the points of constipation, large intestine and rectum of the right ear, and shen men and kidney in the left ear; the seeds will be removed by the researcher every 3-days in face-to-face meetings and at least 1-2 hours later, another vaccaria seed will be located on the same point. The patients are instructed to press the seeds 8

times a day for one minute each time.

Category

Treatment - Devices

2

Description

Control group:For 10 sessions with three days interval (30 days in total), non-vaccaria seeds will be located on the false points of both ears. The seeds will be removed by the researcher and her colleague every 3-days in face-to-face meetings and at least 1-2 hours later, another non-vaccaria seed will be located on the same point.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Houri Lahijanian

Street address

Alzahra hospital., Blvd Sofeh

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2

Recruitment center

Name of recruitment center

Noor and Ali Asghar hospital

Full name of responsible person

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Street address

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3

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Houri Lahijanian

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4

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nahid Shahgholian

Street address

Hezar Jereyb St., Isfahan University of Medical Sciences

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Houri Lahijanian

Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

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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