

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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)

Phone

+98 31 3266 8042

Email address

h.lahijanian@nm.mui.ac.ir

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

Isfahan

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

Houri Lahijanian

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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Amin hospital.,Ebne Sina Ave

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4

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Houri Lahijanian

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Farabi hospital., Blvd Arghavanieh

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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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8174673465

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shahgholian@nm.mui.ac.ir

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

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nahid Shahgholian

Position

Instructor

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Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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