

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of reflexology on nausea and vomiting of hemodialysis patients

Protocol summary

2018-02-11, 1396/11/22

Study aim

The aim of this study was to provide a simple executive solution to reduce nausea and vomiting in hemodialysis patients.

Design

Randomized; double blind; single-center clinical trial.

Settings and conduct

The present study will be conducted at "Hami Dialysis Center" in Arak, and on hemodialysis patients. The samples and the data analyzer will not know how to place the samples in the intervention and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: nausea and vomiting due to hemodialysis; conduct at least two dialysis sessions per week; have at least 3 months of dialysis history; 18-65 years old; no use of other complementary therapies during the study. Exclusion criteria: unwillingness to participate in the study; acute infection in the foot; stroke with sensory-motor problems.

Intervention groups

After receiving permission from the patient and explaining the procedure, foot reflexology massage will be performed for the intervention group and for the control group, massage will be performed on the shin of legs.

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161210031328N7**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

Registration date

Registrant information

Name

Mahbobeh Sajadi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

m.sajadi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of reflexology on nausea and vomiting of hemodialysis patients

Public title

The effect of reflexology on nausea and vomiting of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Nausea and vomiting due to hemodialysis Willingness to

collaborate in the study Conduct at least two hemodialysis sessions per week Have at least 3 months of hemodialysis history Absence of skin disease with leg involvement Lack of coagulation disorders Age between 18 to 65 years old Non-use of other complementary therapies during the study

Exclusion criteria:
The patient's unwillingness to collaborate in the study
Acute infection or ulcer in the leg Stroke and sensory-motor problems in the leg

Age
From **17 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are divided into intervention and control groups using randomized block allocation method.

Blinding (investigator's opinion)
Double blinded

Blinding description
Samples and researcher will not know how to allocate to the intervention and control group.

Placebo
Not used

Assignment
Parallel

Other design features
Samples were randomly assigned to two intervention and control groups using randomized block allocation method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Alam al hoda St, Rah ahan Sq

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-01-14, 1396/10/24

Ethics committee reference number

IR.ARAKMU.REC.1396.242

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

Nausea and

ICD-10 code description

R11

Primary outcomes

1

Description

Nausea due to hemodialysis

Timepoint

Daily and after intervention

Method of measurement

Using the VAS tool (Visual Analog Scale)

2

Description

Vomiting due to hemodialysis

Timepoint

Daily and after intervention

Method of measurement

Counting the number of vomiting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: An intervention 1-2 hours after the onset of hemodialysis in the area of nausea and vomiting is done three days a week, for 4 weeks, 12 sessions and 30 minutes each time.

Category

Treatment - Other

2

Description

Control group: Massage is done an unrelated point with nausea and vomiting (legs).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak dialysis center of Hami

Full name of responsible person

Hossein Sarmadian

Street address

Sadi St, Ferdosi St, Ab Sq, Gerdou St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

Vice Chancellor for research, Piambar Azam university complex, sardasht region

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Vahid Naseri Salahshour

Position

MSc Student of Nursing in Medical Surgical Field

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Mahbobeh Sajadi

Position

Associate professor

Latest degree

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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

Mahbobeh Sajadi

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Other areas of specialty/work

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.

When the data will become available and for how long

The beginning of the access period is 18 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In order to utilize scientific purposes and mention the source used.

From where data/document is obtainable

Dr Mahboubeh Sajjadi, Ph.D. of Nursing, Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Arak, Iran. E-mail address: sajadimahbobeh@yahoo.com

What processes are involved for a request to access data/document

After receiving the email from the requester, the information will be sent within 2 to 3 business days.

Comments