Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology on relief ، muscle cramp and nausea during hemodialysis in patients undergoing hemodialysis in the selected military hospital.

Protocol summary

Study aim
Determining the effect of foot reflexology massage on comfort, muscle cramp and nausea during hemodialysis of patients undergoing hemodialysis in army hospital.

Design
Clinical trial with two intervention and control groups, double-blind, randomized, random allocation by variable blocks of 4, sample size 52 patients, reflexology in the intervention group and normal massage in the control group.

Settings and conduct
Study in the Dialysis Department of Selected Military Hospital in Tehran, blinding of patients and the analyst, performing foot reflexology in the intervention group and normal massage in the control group, assessing comfort, muscle cramps and nausea before and after the intervention.

Participants/Inclusion and exclusion criteria
Entry requirements: The study population includes hemodialysis patients in a selected military hospital in Tehran who meet the inclusion criteria. Non-entry conditions: Unwillingness to participate in research

Intervention groups
In the intervention group, the researcher will perform a reflex massage on both feet of the patient (each foot for 15 minutes) for a total of half an hour, then in the area under the patient's toes in the reflex area related to the kidneys (In areas 2 and 3 in the midline of the foot (in the middle part under the big toe) is the area related to digestive problems to reduce nausea, the solar plexus area for comfort and reducing muscle cramps, and also the area related to the sciatic nerve, which is above the heel and close to The massage center will be done for each leg for 15 minutes.this intervention is performed once per session and for three consecutive hemodialysis sessions (per week). For the control group, reflexology massage is performed three times a week in false points.

Main outcome variables
Inducing comfort; Reducing muscle cramps during dialysis; Reducing nausea

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230122057181N1**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date
2023-06-06, 1402/03/16

Registrant information
Name
Mehran Sajadian
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-30, 1402/03/09
Expected recruitment end date
2023-08-02, 1402/05/11
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of foot reflexology on relief ، muscle cramp and nausea during hemodialysis in patients undergoing hemodialysis in the selected military hospital.

Public title
Investigating the effect of foot massage on comfort, muscle cramps and nausea
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years and below 75 years At least 6 months under hemodialysis treatment Dialysis three or more times a week Absence of acute infection Absence of muscular-skeletal disorders such as multiple sclerosis, severe heart and respiratory failure mentioned in the patient's medical history or mentioned by the patient and companions Absence of chronic inflammatory disease of unknown origin Absence of skin diseases on the feet (such as psoriasis, fungal diseases, any wounds, including diabetic foot ulcers) absence of thrombosis and blood supply disorders Not using drugs, alcohol and smoking
Exclusion criteria:
Unwillingness to continue cooperation or the occurrence of any complications Absence of more than two sessions during study Skin sensitivity or allergy to lubricant gel Hemodynamic disturbance during hemodialysis such as severe drop in blood pressure A history of hospitalization in neuropsychiatric departments or taking neuropsychiatric drugs Use of anti-nausea drugs before reflexology massage Confirmation of any of the problems and diseases mentioned in the entry criteria during the study
Age
From **18 years** old to **75 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients eligible to be included in the study based on the criteria of random allocation by variable blocks method (if A: intervention group, B: control group, there will be six different states for blocks of 4: 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB that blocks can be written on paper and taken from inside the bag) will be distributed in two groups. In this way, after explaining the method and objectives of the study to the patients and, if necessary, their families and obtaining informed consent from them, they are randomly assigned to two intervention and control groups. In this way, the first patient will be in the intervention group and the second patient will be in the control group, and the same will be observed until the last patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
Because the properties of chronic diseases and chronic hemodialysis patients are influenced by each other so that they have a great influence on each other from their experiences. In order to prevent this from happening and for the patients' answers in the questionnaires to be real and not influenced by other patients, we separated the intervention and control groups, so that even days the intervention group receives the desired massage and Individuals in the control group receive the usual intervention in the dialysis department. In this way, they did not face each other and the control group did not see the desired massage and intervention.
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Army Medical Sciences University
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Aja university, Etemadzade Ave, Docter fatemi Ave, Shariati Blvd
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Province
Tehran
Postal code
1411718541
Approval date
2022-11-20, 1401/08/29
Ethics committee reference number
IR.AJAUMS.REC.1401.122

Health conditions studied

1

Description of health condition studied
Hemodialysis, dialysis, reflexology massage
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comfort score in Kolkaba General Comfort Questionnaire
Timepoint
Before and after the intervention
Method of measurement
(Kolkaba General Comfort Questionnaire to measure comfort)

2

Description
Nausea score in Rhodes index of nausea and vomiting
Timepoint
Before and after the intervention
Method of measurement
Rhodes index of nausea and vomiting

3

Description
Number of muscle cramps during hemodialysis
Timepoint
Before and after the intervention
Method of measurement
Numeric scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The researcher will perform reflex massage on both feet of the patient (each foot for 15 minutes) and for a total of half an hour. A slippery substance such as lubricant gel is used. In the area under the patient's toes, in the reflective area related to the kidneys (in areas 2 and 3 in the middle line of the foot), in the middle part under the big toe, the area related to digestive problems to reduce nausea, the solar plexus area for comfort and reducing cramps. Muscular as well as the part related to the sciatic nerve which is above the heel and close to the center of the massage will be done for each leg for 15 minutes. In general, for all people in the intervention group, the massage will start from the right foot and last 30 minutes in total. This intervention is performed once per session and for three consecutive hemodialysis sessions (per week). For the intervention group, before the reflex massage, at the beginning of the week, Kolkaba's general comfort questionnaire and the Rhodes questionnaire will be provided to them to assess nausea and will be completed by them. It will be done at the end of the week, and at the end of the week, comfort and nausea questionnaires will be provided to the patients, and muscle cramp monitoring will be done.
Category
Treatment - Other

2

Description
Control group: For the control group, reflexology massage is performed three times a week on false points and points other than the 2nd and 3rd midline of the foot, under the big toe and the solar plexus area, which are the study points of the researcher. The massage will be performed by a trained researcher and will be performed with the thumb in the form of sliding and sliding movements. Due to ethical considerations and non-acceptance of female patients to perform reflex massage on the soles of the feet, the intervention will only be performed for male patients of the hemodialysis department. The pressure will be in such a way that resistance and stiffness will be felt under the thumb. No intervention will be done for the control group. For these patients, according to the plan (on odd days of the week), questionnaires will be given to them at the beginning of the week, and at the end of the week, the questionnaires will be completed by them again and information will be collected.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatullah Hospital
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1

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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
Artesh 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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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Potential data can be shared after the completion of the research and after de-identifying people, for example, data such as pre- and post-intervention questionnaires regarding nausea and vomiting, comfort and cramps, etc. can be shared. .

When the data will become available and for how long

The start of the access period from the second half of 2023

To whom data/document is available

Data can be accessed by all researchers working in academic and scientific centers or even researchers personally.

Under which criteria data/document could be used

Analyzes related to this research so that this similarity completes the previous research. Also, for the final access to the data and analysis, it is necessary for the person to send his/her profile and request to my email in order to receive the desired information as soon as possible. I will send it to them.

From where data/document is obtainable

To use the data, please send a request to the address mh.sajadian@gmail.com or to the library of the Faculty of Nursing of Army University of Medical Sciences located in Tehran, Shariati St., in front of Bahar Shiraz St., Kaj St., next to the Army Family Hospital, Faculty of Nursing Request and study student's reference and thesis from this library.

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

From the time I receive the email and review it, I will respond to it as soon as possible... To estimate the response time, the requested information and data will be sent to Ishal within three days of receiving the email.

Comments

To send a request for information, first send it to the email address: mh.sajadian@gmail.com and if the desired answer is not received within three days, send your request to the email address afaghi8181@gmail.com.