Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of abdominal massage on constipation and laboratory indicators in hemodialysis patients

Protocol summary

Study aim
Determining the effect of abdominal massage on constipation and laboratory indicators in hemodialysis patients

Design
The sample of this research will be hemodialysis patients with chronic constipation, which due to the limited population under study and the high inclusion criteria, all the hemodialysis patients of Shafa Hospital (82 people) and Javad Al-Aimeh Clinic (180 people) in terms of inclusion criteria are studied.

Settings and conduct
Using the patient's file, the researcher will determine the list of people eligible to enter the study according to the entry and exit criteria of the patients, and then enter them into the study through a table of random numbers. The samples will be randomly allocated into two abdominal massage groups (intervention) and sham group (control).

Participants/Inclusion and exclusion criteria
• Having a minimum age of 18 years and a maximum of 70 years

Intervention groups
The intervention group receives the intervention three times a week for one month. (The intervention will be done one hour after the start of dialysis and تدئخمهنتعduring dialysis when the patient is connected to the dialysis machine for dialysis and the patient is in a good state in terms of hemodynamic conditions and is ready to receive massage). Immediately after the sessions, the condition of constipation and laboratory indicators and the adequacy of dialysis will be evaluated again in both groups. In this way, after the completion of dialysis and before isolating the patient, in order to take blood to determine the urea after dialysis and calculate the adequacy of dialysis, the standard method of sampling after dialysis is used. For this purpose, the pump will be turned off and the blood sample will be taken from the arterial line in the amount of 2 cc and will be sent to the laboratories of Shafa and Javadalameh centers to check the results.

Main outcome variables
constipation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230205057335N1**
Registration date: **2023-02-08, 1401/11/19**
Registration timing: **prospective**

Last update: **2023-02-08, 1401/11/19**
Update count: **0**

Registration date
2023-02-08, 1401/11/19

Registrant information

Name
Mahdieh Daneshfar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-09, 1402/01/20

Expected recruitment end date
2023-05-10, 1402/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of abdominal massage on constipation and laboratory indicators in hemodialysis patients

Public title
Investigating the effect of abdominal massage on constipation and laboratory indicators in hemodialysis patients referred to Kerman hemodialysis centers in 2023
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a minimum age of 18 years and a maximum of 70 years Having a history of dialysis for at least six months Having a file in the dialysis department of the desired centers Performing at least three times of dialysis per week and four hours each time Not having skin disease, advanced heart failure and stroke The basis of the patient's medical record Constipation according to the CAS constipation severity scale (score greater than 8) Not using anti-constipation drugs do Not having a digestive disorder such as irritable bowel syndrome, fissure anus volvulus, rectal prolapse, intestinal obstruction according to the statement The patient, the patient's file and, if necessary, an examination by a doctor
Exclusion criteria:
Interrupting the study or not completing the intervention (more than two sessions) due to transfer to the acute care department and hospitalization in that department, traveling or not participating in massage therapy sessions for two sessions. • Performing transplant surgery and any surgery in the abdominal area that prevents massage therapy.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **262**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to allocate the studied subjects to intervention and control groups, the block randomization method is used, the block randomization method is a method in which the participants are randomly placed in blocks in terms of cas score, in the following By using simple randomization method and using R software, half of the people from each group will be placed in the intervention group and the other half will be placed in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind. The data analysts do not know which data are related to the intervention and control groups; And the participants do not know which intervention or control group they were placed in. For the intervention group, abdominal massage is performed, while for the control group, a simple abdominal touch is performed.
Placebo
Not 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
Unit. 5, Block B, Bldg Havashenasi, St Shahid kazerooni, Blv Imam reza
City
KERMAN
Province
Kerman
Postal code
7618417739
Approval date
2023-01-09, 1401/10/19
Ethics committee reference number
IR.KMU.REC.1401.468

Health conditions studied

1

Description of health condition studied
constipation
ICD-10 code
k59.0
ICD-10 code description
constipation

Primary outcomes

1

Description
constipation

Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
CAS Constipation Severity Scale

2

Description
Laboratory index of potassium
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Using the information provided in the laboratory sample before and after the intervention

3

Description
Laboratory index of calcium
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Using the information provided in the laboratory sample before and after the intervention

4

Description
Sodium laboratory index
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Using the information provided in the laboratory sample before and after the intervention

5

Description
Laboratory index of phosphorus
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Using the information provided in the laboratory sample before and after the intervention

6

Description
Adequacy of hemodialysis
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Using the information provided in the laboratory sample before and after the intervention

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They receive the intervention three times a week for one month. (The intervention will be done one hour after the start of dialysis and during dialysis when the patient is connected to the dialysis machine for dialysis and the patient is in a good state in terms of hemodynamic conditions and is ready to receive massage).The researcher (woman) and another person (man) will complete the massage course under the supervision of a traditional medicine specialist. The massage lasts 15 minutes. Before the massage, the patient's privacy will be respected and the patient's privacy will be maintained. The way to perform the massage is that the massage is done half an hour before feeding on an empty stomach due to the greater comfort of the patient. In this way, the patient is placed in a lying position on the back so that the legs are slightly bent from the knees and the head is at an angle of 15 to 30 degrees. The covering of the massage area is removed from the anterior upper surface of the iliac crest to below the lower ribs of the chest and other parts of the body remain covered. Then the masseur will be placed on the right side and in front of the lower level of the patient's pelvis and will start the massage. The massage will start clockwise from the beginning of the ascending colon and continue towards the horizontal colon and finally to the end of the descending colon. Massage in Swedish massage style including touching or stroking movements, exfoliation with head movements, vibration and kneading movements with palms or needing will be done twice for each patient. It should be noted that no oil or lotion is used for the massage. Also, in order to prevent the distortion of information, performing abdominal massage at home is controlled by the patient.
Category
Treatment - Other

2

Description
Control group: In the sham group, a simple palpation of the abdomen is performed, and immediately after the sessions, the condition of constipation and laboratory indicators and the adequacy of dialysis will be evaluated again in both groups.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center

Shafa Kerman Hospital

Full name of responsible person
Mahdieh Daneshfar

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Web page address
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2

Recruitment center

Name of recruitment center
Javad Alaima Clinic

Full name of responsible person
Mahdieh daneshfar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abas Pardakhti

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https://kmu.ac.ir

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
Kerman University of Medical Sciences

Full name of responsible person
Mahdieh Daneshfar

Position
Masters

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Position
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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
Not applicable