

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 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). 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

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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 needling 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
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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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
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Position
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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