

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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)

##### Phone

+98 34 3331 2299

##### Email address

mahdieh.daneshmand6430@gmail.com

##### 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  
**Full name of responsible person**  
Mahdieh Daneshfar  
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Shafa Ave  
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mahdieh.daneshmand6430@gmail.com  
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http://kmu.ac.ir

## 2

### Recruitment center

**Name of recruitment center**  
Javad Alaima Clinic  
**Full name of responsible person**  
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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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Kerman University of Medical Sciences, Haft Bagh  
Alavi Blv,  
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**Province**  
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**Email**  
ABPARDAKHTY@KMU.AC.IR  
**Web page address**  
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**  
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## Person responsible for scientific inquiries

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**Person responsible for updating data**

**Contact**

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**Position**

Masters

**Latest degree**

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**Other areas of specialty/work**

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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