

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### Effect of exercise with mini bike on fatigue, sexual function and dialysis adequacy in Hemodialysis patients

#### Protocol summary

##### Study aim

Determination of the effect of small bicycle exercise on tiredness, sexual function and dialysis adequacy in hemodialysis patients

##### Design

Clinical trial study with control group with parallel, randomized, non-blinded groups

##### Settings and conduct

Study setting: hemodialysis centers affiliated with Kerman University of Medical Sciences including dialysis department of Shafa hospital and dialysis center of Javad Alameh. How to do the study: Patients are divided into two groups of intervention and control. The intervention group will exercise for 20 minutes. Sexual function and fatigue questionnaire are completed by them. The control group does not receive intervention and only completes the questionnaire of sexual function and fatigue. This work is done for 3 months.

##### Participants/Inclusion and exclusion criteria

"Inclusion" At least 3 months have elapsed since the start of their dialysis, Hemodialysis is performed twice a week and for 4 hours, The spouse is still alive, People between 18 and 76 years old; "Exclusion" Parathyroid hormone above 1000, Diabetic wound in the legs, The spouse's death, Divorce

##### Intervention groups

Intervention group: Patients undergoing hemodialysis exercise with small bicycles during dialysis for 3 months, twice a week and 20 minutes. Control group: Patients undergoing hemodialysis do not receive an intervention and routine care is provided to them.

##### Main outcome variables

Sexual function, Fatigue, Adequacy of dialysis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180314039100N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

##### Registration date

2018-10-06, 1397/07/14

##### Registrant information

###### Name

Farzaneh Salehi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3211 5813

###### Email address

farzaneh.salehi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-31, 1397/03/10

##### Expected recruitment end date

2018-09-01, 1397/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of exercise with mini bike on fatigue, sexual function and dialysis adequacy in Hemodialysis patients

##### Public title

Effect of exercise with mini bike on Hemodialysis

patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
At least 3 months have elapsed since the start of their dialysis Hemodialysis is performed twice a week and for 4 hours The spouse is still alive People between 18 to 76 years old  
**Exclusion criteria:**  
Parathyroid hormone above 1000 Diabetic wound in the legs Prohibition on exercising The spouse's death Divorce Remarriage People with heart disease Orthopedic problems in the lower extremities

**Age**  
From **18 years** old to **76 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible patients are selected by census method and then, according to the entry conditions, they are randomly assigned to the intervention and control groups by lottery. Draw coins are used. So that each coin is thrown. Patients who have shape for them are in the intervention group and for those who come to the line they are in the control group. Both groups will be matched in terms of age and gender.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**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**  
Shafa hospital, end of Shafa street, Jomhuri boulevard  
**City**  
Kerman  
**Province**  
Kerman

**Postal code**  
7618751151

**Approval date**  
2018-06-12, 1397/03/22

**Ethics committee reference number**  
IR.KMU.REC.1397.086

## Health conditions studied

### 1

**Description of health condition studied**  
Chronic renal failure

**ICD-10 code**  
N18

**ICD-10 code description**  
Chronic kidney disease

## Primary outcomes

### 1

**Description**  
The score of exercise with minibike

**Timepoint**  
Before the intervention, one month after the intervention, two months after the intervention, three months after the intervention, one month after the end of the intervention

**Method of measurement**  
Fatigue Questionnaire, Sexual Function and Dialysis Sufficiency

## Secondary outcomes

### 1

**Description**  
Sexual function

**Timepoint**  
Before starting study and then every month during 3 months and 1 month after finishing study

**Method of measurement**  
Sexual Function Questionnaire

### 2

**Description**  
Fatigue

**Timepoint**  
Before starting study and then every month during 3 months and 1 month after finishing study

**Method of measurement**  
Fatigue questionnaire

### 3

**Description**  
Adequacy of dialysis

**Timepoint**  
Before starting study and then every month during 3 months and 1 month after finishing study

## Method of measurement

The software calculates the adequacy of dialysis (kt/v)

## Intervention groups

### 1

#### Description

Intervention group: Intervention will be using a small bicycle. In this research, bikes will be used with electric power for easy pedaling. The bicycle is placed on the bed immediately and connected to the dialysis device immediately after attaching the patient. The timer is set to 20 minutes and the key is started. Before starting exercise, the patient's blood pressure will be measured to determine the clinical condition. The Exercises with a small bike will be done twice a week and at the beginning of dialysis for 20 minutes. It will be continue for 12 weeks.

#### Category

Rehabilitation

### 2

#### Description

Control group: There is no intervention in the control group and they will receive routine care as usual.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shafa hospital

##### Full name of responsible person

DR. Parvin Mangolian

##### Street address

Shafa hospital, end of Shafa street, Jomhuri Boulevard

##### City

Kerman

##### Province

Kerman

##### Postal code

7618751151

##### Phone

+98 34 3211 5811

##### Fax

+98 34 3211 5803

##### Email

mangolian167@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Abbas Pardakhti

##### Street address

Kerman University of Medical Sciences, Medical University Compus, Haft-Bagh Highway, Kerman, Iran

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3226 3855

##### Email

vcr@kmu.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### 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

Farzaneh Salehi

##### Position

MSc student

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Shafa hospital, end of the Shafa street, Jomhuri boulevard

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7617894593

##### Phone

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Farzaneh Salehi

**Position**

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**Email**

farzanehsalehi3@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Unidentifiable data from individuals and related information will be shared with other researchers Study protocol, data analysis program, etc, will be shared

**When the data will become available and for how long**

Access to data is always available.

**To whom data/document is available**

All researchers are allowed to use.

**Under which criteria data/document could be used**

Data can be used for research on variables and the provision of new solutions with the mention of the reference.

**From where data/document is obtainable**

See the email of the researcher or the journal in which the article has been published

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

Search in the Internet by using keywords and selecting titles or requesting them by sending an email to the researcher

**Comments**