

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

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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

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7616913555

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Farzaneh salehi

Position

MSc student

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

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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