Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Investigating the effect of active exercise during dialysis on uremia and hyperphosphatemia in hemodialysis patient

Protocol summary

Study aim
The effects of active exercises during dialysis on uremia and hyperphosphatemia in hemodialysis patients

Design
This study is a randomized clinical trial, two groups (intervention and control group), one blind strain, with a sample size of approximately 66 patients. Minimization software will be used for randomization.

Settings and conduct
The location of the study will be the dialysis department of Khurshid Hospital, Isfahan. At first, the letter of introduction to conduct the research will be presented to the head of the department, and then the sampling will be done, the sports program under study will be taught and it will be done in each dialysis session under the supervision of the researcher. Finally, the blood sample will be sent to check and compare the results. Blinding will be done by the data analyst.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, fixed number of dialysis sessions per week, length of dialysis period more than 3 months, ability to perform active range of motion exercises and pedaling independently, ability to teach exercises, stable hemodynamics during sessions Hemodialysis. Exclusion criteria: pregnancy, history of cardiovascular and pulmonary diseases and strokes, uncontrolled blood pressure, uncontrolled diabetes.

Intervention groups
Each sample in the intervention group started a sports program including active joint range of motion exercises by raising and lowering the limbs and rotating movements, and then in the following weeks, according to the protocol, they started pedaling a stationary bike or a mini bike while will do dialysis. The control group only received routine care during dialysis.

Main outcome variables
blood urea and phosphorus clearance; adequacy of dialysis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230704058663N1**
Registration date: **2023-08-16, 1402/05/25**
Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**
Update count: **0**

Registration date
2023-08-16, 1402/05/25

Registrant information
Name
Elham Hasani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3444 9589
Email address
eli.hsni1996@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2023-09-06, 1402/06/15

Actual recruitment start date
2023-08-23, 1402/06/01

Actual recruitment end date
2023-09-11, 1402/06/20

Trial completion date
2023-11-11, 1402/08/20

Scientific title

Investigating the effect of active exercise during dialysis on uremia and hyperphosphatemia in hemodialysis patient

Public title

Investigating the effect of exercise during dialysis on blood phosphorus and urea clearance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All dialysis patients who are over 18 years old. All dialysis patients who have a fixed number of sessions per week and undergo hemodialysis 3 times a week and each session lasts for 4 hours. All dialysis patients who have undergone hemodialysis for more than 3 months. All dialysis patients who use a permanent vascular access. All dialysis patients who are able to perform active range of motion exercises and pedal independently. All dialysis patients who have the ability to learn exercises and do not have mental disabilities. All dialysis patients who had stable hemodynamics during hemodialysis sessions in the last 1 month.

Exclusion criteria:

pregnancy. Patients with symptomatic and severe aortic stenosis Patients who have a history of lung disease that requires oxygen therapy Patients who do not have a history of stroke or transient ischemic attacks in the last 3-6 months Patients who have a history of heart attack and unstable angina in the past 3-6 months. Patients with a history of ischemic heart disease Patients who have any disorders in the musculoskeletal system (orthopedic problems, lower limb amputations, etc.) that prevent them from performing the desired sports activities Patients with uncontrolled blood pressure. Patients with uncontrolled diabetes. Patients who have a history of moderate to severe heart failure (class ≥II according to New York Heart Association criteria). Patients with a history of angina pectoris grade 2-4 according to the criteria of the Canadian Heart and Vascular Association

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The replacement of samples in the groups will be done in the form of random allocation using the minimization method. Minimization is done using MiniPie software (http://minimpy.sourceforge.net). Considering the fact that the distribution of urea in the body of patients undergoing hemodialysis (distribution volume of urea) depends on the age, gender, height and weight of the patient, therefore the parameters of age, gender, height and weight for the random allocation of samples in the soft Software will be defined. After selecting the samples in an easy way, the research associate will give a unique number to the sample and after entering the defined variables into the software, the application will place the patient in the test or control group. In other words, the information of 66 patients enters the software, the software will place 33 patients in the test group and 33 patients in the control group. If the software puts a patient with a certain age, sex, height and weight in the test group, it tries to put a similar patient in the control group in terms of the mentioned characteristics, and if there is no similar sample in the 66 entered list. Sampling will continue until the desired number of samples is provided in both groups and the samples are homogeneous.

Blinding (investigator's opinion)

Single blinded

Blinding description

It is not possible to be blinded by the researcher and the samples, but blinding will be done by the analyst or statistician.

Placebo

Not used

Assignment

Other

Other design features

The groups participating in the study receive an independent intervention or no intervention (control group).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Street, Isfahan University of Medical Sciences, Building No. 3, Faculty of Medicine, Ground Floor, Department of Medical Ethics

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.MUI.MED.REC.1402.129

Health conditions studied

1

Description of health condition studied
Hyperphosphatemia
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

2

Description of health condition studied
Uremia
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Blood phosphorus level
Timepoint
At the beginning of the study (before the start of the intervention) and 1 and 2 months after the start of the intervention
Method of measurement
Sending the blood sample to the laboratory

2

Description
Blood urea level
Timepoint
At the beginning of the study (before the start of the intervention) and 1 and 2 months after the start of the intervention
Method of measurement
Sending the blood sample to the laboratory

Secondary outcomes

1

Description
Quality of life
Timepoint
mortality
Method of measurement
hospitalization

Intervention groups

1

Description
Intervention group: Intervention group: They will perform an exercise program including active range of motion exercises for 2 weeks and then pedaling a stationary bike or a mini bike for 6 weeks during dialysis. The suggested duration of exercise in each session will gradually increase depending on the patient's ability. Exercise intensity is also measured using standard tools.
Category
N/A

2

Description
Control group: receive routine care during dialysis, including control of vital signs, self-care training, care of vascular access, daily visit of a specialist doctor, nutritional advice, daily weighing in each dialysis session.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid hospital
Full name of responsible person
Dr. Shahrazad Shahidi
Street address
No. 105, Ostandari Street, khorshid medical educational research complex.
City
Isfahan
Province
Isfehan
Postal code
81458-33117
Phone
+98 31 3222 2127
Email
eli.hsni.1996@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
Street address
Isfahan Province, Isfahan, Hezar Jerib Avenue.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
eli.hsni1996@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Elham Hasani
Position
Master student of Critical Care Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
12 Shohada Alley, Shohada St.
City
Lordegan
Province
Chahar-Mahal-va-Bakhtiari
Postal code
88916-83915
Phone
+98 38 3444 9589
Email
eli.hsni.1996@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Elham Hasani
Position
Master student of Critical Care Nursing
Latest degree
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Other areas of specialty/work
Nursery
Street address
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Postal code
88916-83915
Phone
+98 38 3444 9589
Email
eli.hsni.1996@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Elham Hasani
Position
Master student of Critical Care Nursing
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Other areas of specialty/work
Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information on the main outcome will be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available

The request of all the people who want to access the data will be answered.

Under which criteria data/document could be used

In order to use the protocol in the hospital, to implement the protocol in rehabilitation centers, in cases where it has a supportive and therapeutic aspect for the patient, mention the study results in other researches.

From where data/document is obtainable

Respondent: Elham Hasani Email address: eli.hsni1996@gmail.com

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

After receiving the email, it will be answered within 48 hours.

Comments