Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of stationary cycling exercise during dialysis on dialysis adequacy and laboratory parameters of hemodialysis patients

Protocol summary

Study aim

Objective: To evaluate the effect of stationary cycling during dialysis on dialysis adequacy and laboratory and hemodynamic parameters of hemodialysis patients in Isfahan. Specific Objectives: To compare baseline, laboratory, Kt/V, and hemodynamic parameters before and after the study between intervention and control groups.

Design

Parallel-group clinical trial with 70 hemodialysis patients (35 per group) randomized via Simple Randomize. Data analyst blinded.

Settings and conduct

Eligible patients in Isfahan are randomly assigned to intervention or control.

Participants/Inclusion and exclusion criteria

Age ≥ 18 years Written informed consent Chronic kidney failure on maintenance hemodialysis ≥ 3 months At least 3 hemodialysis sessions per week No hospitalization in the past month No diagnosed psychiatric or cognitive disorders Physically able to perform exercise on a stationary bicycle during dialysis Exclusion Criteria (Not eligible to participate): Age < 18 years Lack of written informed consent Hemodialysis < 3 months or not on maintenance hemodialysis Fewer than 3 hemodialysis sessions per week Hospitalization within the past month Diagnosed psychiatric or cognitive disorder Not physically fit to exercise on a stationary bicycle during dialysis

Intervention groups

Participants in the intervention group will exercise on a stationary bike during hemodialysis sessions. The control group will receive standard hemodialysis care without exercise

Main outcome variables

Dialysis adequacy; laboratory and hemodynamic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250819066916N1**
Registration date: **2025-08-29, 1404/06/07**
Registration timing: **prospective**

Last update: **2025-08-29, 1404/06/07**
Update count: **0**

Registration date

2025-08-29, 1404/06/07

Registrant information

Name

Mohammad Matinfar

Name of organization / entity

Islamic Azad University, Najafabad Branch • Isfahan Kidney Diseases Research Center

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-21, 1404/06/30

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of stationary cycling exercise during dialysis on dialysis adequacy and laboratory parameters of hemodialysis patients

Public title
The effect of exercise during dialysis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age over and equal to 18 years Written informed consent to participate in the study Diagnosis of chronic kidney failure and receiving maintenance hemodialysis for at least 3 months Undergoing at least 3 hemodialysis sessions per week No hospitalization within the past month No diagnosed psychiatric or cognitive disorders Having the physical ability to perform exercise on a stationary bicycle during dialysis

Exclusion criteria:
Age less than 18 years Lack of written informed consent to participate in the study Not having chronic kidney disease and receiving hemodialysis for less than three months Having fewer than three hemodialysis sessions per week Hospitalization within the past month Have a diagnosed psychiatric or cognitive disorder Not being physically fit enough to exercise on a stationary bike during dialysis

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants were assigned to the intervention or control group using simple randomization through the Simple Randomize software. Randomization was performed at the individual level, and allocation concealment was ensured by the software so that neither researchers nor participants could predict group assignment prior to enrollment.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the intervention (using a cycle ergometer during hemodialysis), participants cannot be blinded to their group assignment, as the physical experience of the intervention is observable and tangible. However, to minimize bias in data collection and analysis, the following measures were implemented: Clinical caregivers and healthcare personnel responsible for patient care were kept unaware of group allocation, and uniform care protocols were applied to all patients so that the intervention effect could not be distinguished from routine care. Data collection was conducted by a team member who knew the group assignments; however, data were coded and provided to the data analyst in a de-identified manner. The data analyst remained blinded to the group assignment, and all analyses were performed based on anonymized codes. The principal investigator and study conductors had no access to individual group assignments, ensuring that decisions and analyses were independent of group allocation. The Data Safety and Monitoring Committee (DSMC), if applicable, could access anonymized data but no information regarding specific group assignments was disclosed to the analyst or clinical staff. Thus, although participants could not be blinded due to the nature of the intervention, clinical caregivers, data collectors, and the analyst were effectively blinded to minimize potential bias and preserve the validity of the study results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences – Al-Zahra Research Centers

Street address
No. 4 Building, Vice-Chancellery for Research and Technology, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

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Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2025-08-18, 1404/05/27

Ethics committee reference number
IR.ARI.MUI.REC.1404.105

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Dialysis adequacy (Kt/V)
Timepoint
Dialysis adequacy (Kt/V) is measured at three time points: baseline, week 4 (mid-study), and week 8 (end of study).
Method of measurement
Dialysis adequacy (Kt/V) is calculated by collecting blood samples before and after dialysis and entering the laboratory results and dialysis parameters into the corresponding formula.

2

Description
Laboratory parameters (hemoglobin, creatinine, etc.)
Timepoint
Laboratory parameters is measured at three time points: baseline, week 4 (mid-study), and week 8 (end of study).
Method of measurement
Laboratory parameters are collected according to standard procedures at the beginning of the dialysis session before starting dialysis from a fasting patient.

Secondary outcomes

1

Description
Hemodynamic parameters (systolic and diastolic blood pressure, pulse, and oxygen saturation)
Timepoint
Hemodynamic parameters, including blood pressure, pulse, and oxygen saturation, are monitored at three time points: the beginning of the study, mid-study (week four), and the end of the study (week eight), both before and after dialysis.
Method of measurement
Hemodynamic parameters are monitored at the patient's bedside using calibrated blood pressure monitors and pulse oximeters.

Intervention groups

1

Description
Intervention group: Patients in the intervention group will undergo intradialytic exercise using a stationary bicycle for 8 weeks (2 months), three sessions per week, concurrently with their hemodialysis. The exercise will be performed on a stationary cycle ergometer available in the dialysis center, positioned next to the patient's bed. Each session will be conducted during the first two hours of dialysis and will last for 20 minutes. Exercise protocol: 5 minutes of warm-up, two sets of 10 minutes cycling with an initial resistance of 20 watts and intensity adjusted to the patient's individual capacity, with a 2-minute rest between sets, followed by 5 minutes of cool-down. The exercise intensity will be progressively increased based on the patient's condition until continuous 20-minute cycling is achieved.All exercise sessions will be supervised by the researcher and the dialysis nurse. If any adverse symptoms such as severe dyspnea, chest pain, hypotension, or marked weakness occur, the exercise will be immediately discontinued.
Category
Rehabilitation

2

Description
Control group: Patients in the control group will receive only their routine hemodialysis treatment according to the standard protocol of the center, without any additional exercise intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Abolfazl Charity Hemodialysis Center
Full name of responsible person
Mohammad Matinfar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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No. 4, Research and Technology Deputy, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

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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
Mohammad Matinfar
Position
Nephrologist, Faculty Member of the Nephrology Department
Latest degree
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available