Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative evaluation of the effects of Intradialytic versus Interdialytic exercises on clinical outcomes in Hemodialysis patients

Protocol summary

Study aim
Determining and comparing the effects of intradialytic versus interdialytic exercises on clinical outcomes and patient preferences in maintenance hemodialysis patients

Design
Crossover clinical trial without an independent control group, 50 patients, random allocation using a random number table and sealed opaque envelopes. Group A: first intradialytic exercise, then washout, then interdialytic exercise. Group B: reverse order.

Settings and conduct
The study is conducted in the hemodialysis centers of Imam Khomeini, Amir Alam, and Shariati hospitals. Fifty eligible patients are randomly allocated to two groups A and B, and single-blind blinding (laboratory technician and statistician) is performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-65 years, regular hemodialysis ≥12 hours/week with history ≥3 months, clinical stability, physician approval, informed consent. Exclusion criteria: Cardiovascular or hemodynamic instability, active infection or acute illness, fasting blood glucose <70 or >250 mg/dL, new musculoskeletal disorder, kidney transplantation during study, desire to withdraw.

Intervention groups
Intradialytic exercise: During the first two hours of dialysis: warm-up, stationary bike, lower limb resistance/balance exercises, cool-down. Interdialytic exercise: At home on non-dialysis days: warm-up, walking, lower limb resistance/balance exercises, cool-down. Control: Crossover trial without independent control group; each patient receives both interventions with a washout period between them.

Main outcome variables
Dialysis adequacy, inflammatory factors, nutritional factors, quality of life, independence in activities of daily living, sleep quality, patient preferences

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251208068248N1**
Registration date: **2026-05-04, 1405/02/14**
Registration timing: **prospective**

Last update: **2026-05-04, 1405/02/14**
Update count: **0**

Registration date
2026-05-04, 1405/02/14

Registrant information

Name
AliReza Yaghoubi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-05, 1405/02/15

Expected recruitment end date
2026-07-22, 1405/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

A comparative evaluation of the effects of Intradialytic versus Interdialytic exercises on clinical outcomes in Hemodialysis patients

Public title

A comparative evaluation of the effects of Intradialytic versus Interdialytic exercises on clinical outcomes in Hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is undergoing regular chronic hemodialysis; at least 12 hours per week. History of at least 3 months of regular dialysis. Body Mass Index (BMI) higher than 18.5 kg/m² and lower than 35 kg/m². Obtaining permission from the attending physician to participate in the study. Willingness and informed consent to participate in the research.

Exclusion criteria:

History of MI in the past 3 months. Musculoskeletal disorders or movement limitations that prevent exercise. Amputation. Presence of vascular access whose function is dependent on body position and risk of bleeding during exercise. Uncompensated heart failure. Uncontrolled hypertension. Severe neurological abnormalities. Lack of access to a treadmill and stationary bike at home for performing the exercises.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a crossover clinical trial without an independent control group, conducted on patients with end-stage chronic kidney disease undergoing maintenance hemodialysis in the hemodialysis centers of Imam Khomeini, Amir Alam, and Shariati hospitals affiliated with Tehran University of Medical Sciences. Sampling will be done using the convenience sampling method, and 50 eligible patients will be selected based on inclusion and exclusion criteria. The random sequence will be generated using a random number table, and allocation of patients to groups A and B will be performed using sealed opaque and numbered envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Nursing and Midwifery and the Faculty of Rehabilitation - Tehran

Street address

No. 1470, North Kargar Street, opposite 16th Street (Farshi Moghaddam), Tehran

City

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Province

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Postal code

1439957181

Approval date

2026-01-08, 1404/10/18

Ethics committee reference number

IR.TUMS.FNM.REC.1404.235

Health conditions studied

1

Description of health condition studied

The condition under study is end-stage renal disease (ESRD), defined as the final stage of chronic kidney disease where kidney function is severely reduced and patients require regular hemodialysis to sustain life.

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Primary Outcome Variables: 1) Dialysis adequacy: Dialysis adequacy measured by Kt/V index, extracted from the patient's monthly laboratory results. 2) Inflammatory factors: Levels of ESR (mm/hour) and CRP (mg/L) measured through blood testing. 3) Nutritional factors: Levels of albumin (g/dL), blood urea nitrogen (mg/dL), serum creatinine (mg/dL), serum cholesterol (mg/dL), sodium (mEq/L), potassium (mEq/L), phosphorus (mg/dL), and calcium (mg/dL) measured through blood testing.

Timepoint

Data will be collected in four stages: 1) before the first intervention (baseline), 2) at the end of the first period (week 4 or 8), 3) at the end of the washout period (week 8 or 12), 4) at the end of the second period (week 12 or 20).

Method of measurement

1) Dialysis adequacy: Kt/V index calculated from the patient's monthly laboratory results 2) Inflammatory factors: Blood test (measurement of ESR and CRP levels) 3) Nutritional factors: Blood test (measurement of albumin, blood urea nitrogen, serum creatinine, serum cholesterol, sodium, potassium, phosphorus, and calcium levels)

Secondary outcomes

1

Description

Secondary Outcome Variables: 1) Quality of life: Quality of life score measured by the standard KDQOL-SF questionnaire (5-point Likert scale, range 0-100). Higher scores indicate better quality of life. 2) Independence in activities of daily living: Independence score in 6 basic daily activities measured by the Katz ADL index (range 0-6). Higher scores indicate greater independence. 3) Sleep quality: Sleep quality score measured by the PSQI questionnaire (range 0-21). A score higher than 5 indicates sleep disturbance. 4) Patient preferences: Patient preference for each of the two exercise methods measured by a researcher-made questionnaire (Likert scale)

Timepoint

Data will be collected in four stages: 1) before the first intervention (baseline), 2) at the end of the first period (week 4 or 8), 3) at the end of the washout period (week 8 or 12), 4) at the end of the second period (week 12 or 20).

Method of measurement

1) Quality of life: Kidney Disease Quality of Life Short Form (KDQOL-SF) questionnaire 2) Independence in activities of daily living: Katz Index of Independence in Activities of Daily Living (Katz ADL) 3) Sleep quality: Pittsburgh Sleep Quality Index (PSQI) questionnaire 4) Patient preferences: Researcher-made questionnaire with Likert scale

Intervention groups

1

Description

First intervention group (Intradialytic exercise): Exercise is performed during the first two hours of the dialysis session. The program includes 5 minutes of warm-up (lower limb stretching), aerobic exercise using a stationary bedside bicycle for 10 to 30 minutes at light to moderate intensity, resistance exercises (leg raising, squeezing a small ball between the knees, knee extension, gastrocnemius muscle strengthening with exercise bands, adduction and abduction with ankle weights and resistance bands), and 5 minutes of cool-down (lower limb stretching). These exercises are performed for 4 to 8 weeks during each dialysis session (three times per week)

Category

Rehabilitation

2

Description

Second intervention group (Interdialytic exercise): Exercise is performed at home on non-dialysis days. The program includes 5 minutes of warm-up (lower limb stretching), aerobic walking for 15 to 30 minutes at light to moderate intensity, resistance exercises (leg raising, squeezing a small ball between the knees, knee extension, gastrocnemius muscle strengthening with exercise bands, toe standing, adduction and abduction with ankle weights and resistance bands, wall-assisted squats after 2 weeks and unassisted squats after 1 month), balance exercises (single-leg standing, and after 3 weeks single-leg standing with eyes closed), and 5 minutes of cool-down (lower limb stretching). These exercises are performed for 4 to 8 weeks, three times per week.

Category

Rehabilitation

3

Description

Control group: This study is a crossover clinical trial without an independent control group. Each patient receives both interventions in two separate periods, and a 4-week washout period without any structured exercise program is considered as the washout phase between the two interventions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
imam khomeini hospital

Full name of responsible person
AliReza Yaghoubi

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Shariati hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
fnm-researchdeputy@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the confidentiality of patient information and the ethical commitment stated in the informed consent form regarding not sharing individual participant data, there is no plan to publish IPD. The research results will only be published as aggregate and group data.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The final research results will be presented in summary form without any individual participant information to the library of Tehran University of Medical Sciences as a thesis report. Also, the overall and group results (in abstract form) will be shared with the authorities of the participating hemodialysis centers. Individual and raw patient data will not be shared due to confidentiality and ethical commitments.
When the data will become available and for how long
Access to the research results will begin after the publication of the main study findings and will remain available for at least 5 years after the completion of the research.
To whom data/document is available
Individual and raw patient data will not be provided to any person or institution. Aggregate and group results (in summary form) will be accessible to academic researchers and authorities of the participating hemodialysis centers. Individuals outside academic and scientific institutions will not have access.
Under which criteria data/document could be used
Aggregate and group research results may be used solely for educational and research purposes with proper citation. Any reuse of data for reanalysis or secondary analyses without permission from the principal investigator is not permitted. Commercial use of the data is prohibited. Requests for access to the results must be submitted in writing to the principal investigator and will be granted after approval by the Ethics Committee. Individual and raw patient data will not be shared under any circumstances.
From where data/document is obtainable
Access to documents is possible through the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences or through the principal investigator's official email, after the request is approved.
What processes are involved for a request to access data/document
The applicant first submits a written request along with their full details and the purpose of using the results via email to the principal investigator. After review and if approved, the request is referred to the Faculty Ethics Committee. Upon final approval, the overall and group results of the study will be provided to the applicant.
Comments