

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the effect of two methods of aerobic and resistance exercises on the adequacy of dialysis and the quality of life in hemodialysis patients

Protocol summary

Study aim

Determination and comparison of the effect of aerobic and resistive exercises on the adequacy of dialysis and quality of life in hemodialysis patients

Design

This is a clinical trial with parallel groups.

Settings and conduct

In this study, the number of samples will be in full compliance with the criteria for inclusion. The sampling is done by referring to the hemodialysis section and selecting the patients who have the criteria for entering the study from the list of patients with fixed section is done. Then, these individuals will be randomly assigned to three groups of aerobic exercise, resistance and control. In this study, the data analyst does not know the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Have at least six months of dialysis history 2. At least twice a week dialysis 3. No known ischemic disease based on history 4. Failure to record the history of heart attacks and angina during the last six months 5. Lung disease requiring artificial oxygen 6. No history of stroke or transient ischemic attacks during the past three months 7. Not having a disturbance in the musculoskeletal system and the leg in the leg that prevents the intended sporting activity (pedaling by bicycle). 8. No use of beta-blocker and no uncontrolled blood pressure 9. Do not interfere with another.

Exclusion criteria: 1- If the patient abstains from at least two sessions of the entire study session. 2. Cancellation of the patient from continuing the study 3. Failure to continue the study for various reasons, such as changing the dialysis process or patient's death

Intervention groups

Aerobic Exercise - Resistance

Main outcome variables

Dialysis adequacy; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042436N2**

Registration date: **2019-05-26, 1398/03/05**

Registration timing: **prospective**

Last update: **2019-05-26, 1398/03/05**

Update count: **0**

Registration date

2019-05-26, 1398/03/05

Registrant information

Name

Mohsen Salari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 74 3323 4115

Email address

salarimo@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two methods of aerobic and resistance exercises on the adequacy of dialysis and the quality of life in hemodialysis patients

Public title

The effect of aerobic and resistance exercise on the adequacy of dialysis and the quality of life of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have at least six months of dialysis history At least twice a week dialysis No known ischemic disease based on history Not having the history of heart attacks and angina during the last six months Lung disease requiring artificial oxygen No history of stroke or transient ischemic attacks during the past three months Not having a disturbance in the musculoskeletal system and the leg in the leg that prevents the intended sporting activity (pedaling by bicycle). No use of beta-blocker and no uncontrolled blood pressure At the same time, there is not under supervision of another study.

Exclusion criteria:

Having known ischemic disease based on history Having a history of heart attacks and angina during the last 6 months. Having pulmonary disease requiring artificial oxygen. Having a history of stroke or transient ischemic attacks in the past three months. Having Disorders of musculoskeletal system in the leg that prevent the exercise (bicycle pedaling). Use of beta-blocker and uncontrolled blood pressure. At the same time, there is under supervision of another study.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, according to the criteria for entering the patients who are willing to participate in the study, they are divided into three groups A, B, and C according to the formula. The two groups are divided into six groups according to formula (2): Draw the first illness in the middle section of the group, select the control group, the aerobic and resistance exercises, in the order indicated in the draw sheet. Again, the selected team will be returned to the Lottery Cup to complete the draw.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the data analyst does not know the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Shahid Dr. Jalil St., Faculty of Nursing, Yasuj

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Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

75919-94799

Approval date

2019-05-10, 1398/02/20

Ethics committee reference number

IR.YUMS.REC.1398.020

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Dialysis adequacy

Timepoint

Before intervention and after intervention

Method of measurement

Formula

2

Description

Quality of life

Timepoint

Before and after the study

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Blood pressure

Timepoint

At the time of the intervention

Method of measurement

With a cardiopulmonary monitoring device

2

Description

Pulse

Timepoint

At the time of the intervention

Method of measurement

With a cardiopulmonary monitoring device

Intervention groups

1

Description

Intervention group: The first intervention group: For resistance exercise, warming up is a simple tensile movement in all four muscle groups in the form of flexion and extension of the elbow joint, the upper and lower sides of the arm.

Category

Rehabilitation

2

Description

The second intervention group: With use of a low-intensity bike, after warming the body for 5 minutes, for 15-60 minutes of exercise, according to protocol. The beginning of exercise for the first week will be as follows. First, a weight will be given to the patient who can only open his hand once (one maximum repetition) and then heals 60 to 65 percent of the weight of the above three training periods To be The number of repetitive exercises will be 8 to 10 times. The rest time will be 1 to 3 minutes after each round of training. The training of the following weeks will be done according to protocol. The duration of resistance exercise starts from 12-15 minutes in the first weeks and ends at 36-48 minutes in the seventh and eighth weeks.

Category

Rehabilitation

3

Description

Control group: Receive routine care.

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Beheshti hospital

Full name of responsible person

Mohsen Salari

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Mohsen Salari

Position

Ph.D. Pediatric Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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