

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of intradialytic aerobic exercise on quality of life, lower limb strength, dialysis adequacy, and hsCRP

Protocol summary

Study aim

Effect of intradialytic aerobic exercise on quality of life, lower limb strength, dialysis adequacy and inflammatory marker

Design

In this randomized controlled clinical trial, 36 patients are enrolled into two groups, intervention and control groups, using randomized block design method by Random Allocation Software.

Settings and conduct

In the hemodialysis center, 36 patients who are randomly divided into control and intervention groups will undergo hemodialysis in two separate environments. After the patient is attached to the hemodialysis machine for 30 minutes, their vital signs are checked and documented. Then the patient starts pedaling for at least 30 minutes. Their vital signs are checked and documented every 15 minutes and also at the end of the exercise.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are on hemodialysis treatment 3 times a week for at least 6 months Exclusion criteria: Existence of underlying cardiopulmonary disease and uncontrolled blood pressure, as well as musculoskeletal problems that make it impossible to cycle.

Intervention groups

In the intervention group, patients will cycle for 6 months at least 3 times a week, for 30 minutes during the first 2 hours of dialysis. Patients in the control group will have their routine hemodialysis at least 3 times a week for 4 hours during the 6 months.

Main outcome variables

Lower Limb Strength; Quality of Life; Dialysis Adequacy; hsCRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080916001256N2**
Registration date: **2020-11-05, 1399/08/15**
Registration timing: **retrospective**

Last update: **2020-11-05, 1399/08/15**

Update count: **0**

Registration date

2020-11-05, 1399/08/15

Registrant information

Name

Maryam Hami

Name of organization / entity

Health Organization

Country

Iran (Islamic Republic of)

Phone

+98 51 1765 9556

Email address

hamim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-07-26, 1399/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intradialytic aerobic exercise on quality of life, lower limb strength, dialysis adequacy, and hsCRP

Public title

Effect of cycling during hemodialysis on patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients who are on hemodialysis treatment 3 times a week for at least 6 months

Exclusion criteria:

Active stable angina History of myocardial Infarction (MI) in the previous month Congestive Heart Failure (CHF) (grade III, IV) Chronic hyperkalemia Active liver disease Musculoskeletal disorders Lower limb amputation Vascular access disorders Resistant Hypertension History of surgery in the previous month Peripheral neuropathy Dementia Malignancies Active Inflammation (Parathormone)PTH>1000 History of femur fracture Poor control diabetes mellitus Intake of immunosuppressant drugs temperature>38' Hemodynamic disorders Cerebrovascular disease Active lung disease Cardiac Ejection Fraction (EF)<45% Hemoglobin<10 g/dL

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks with variable sizes of 4 to 6 with a random sequence of colored leaves are designed in Random Allocation Software and are provided to the secretary in sealed packages. For each patient, one of the envelopes will be opened and the sheet on top is handed to the patient. According to the color of the paper, the patient will be categorized in one of the groups and will be registered in the relevant color list.

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 Mashhad University Of Medical

sciences

Street address

Vice President of Research, Ghoreshi building, Daneshgah st.

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Razavi Khorasan

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91767-99199

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.110

Health conditions studied**1****Description of health condition studied**

Hemodialysis

ICD-10 code

Z49.31

ICD-10 code description

Encounter for adequacy testing for hemodialysis

2**Description of health condition studied**

Chronic kidney disease (CKD)

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

3**Description of health condition studied**

Hemodialysis

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes**1****Description**

Lower Limb Strength

Timepoint

Measuring the duration of Sit-to-Stand 10 test at the beginning of study (before intervention), 3 and 6 months after cycling during hemodialysis (intervention)

Method of measurement

Chronometer

Secondary outcomes**1****Description**

Dialysis Adequacy

Timepoint

Measuring dialysis adequacy at the beginning of study (before intervention), 3 and 6 months after cycling during hemodialysis (intervention)

Method of measurement

Measuring the levels of Urea before and after a dialysis session and calculating dialysis adequacy by collecting blood sample and measuring them with biochemical autoanalyzer

2

Description

Score of quality of life in Kidney Disease Quality of Life Instrument (KDQOL-36)

Timepoint

Measuring the score of quality of life with Kidney Disease Quality of Life Instrument (KDQOL-36) at the beginning of study (before intervention), 3 and 6 months after cycling during hemodialysis (intervention)

Method of measurement

Kidney Disease Quality of Life Instrument (KDQOL-36) Questionnaire

3

Description

High-sensitivity C-Reactive Protein (hs-CRP)

Timepoint

Measuring the plasma levels of High-sensitivity C-Reactive Protein (hs-CRP) at the beginning of study (before intervention), 3 and 6 months after cycling during hemodialysis (intervention)

Method of measurement

Measuring the plasma level of High-sensitivity C-Reactive Protein (hs-CRP) by venous blood sampling and measuring them with biochemical autoanalyzer

Intervention groups

1

Description

Intervention group: In the hemodialysis center, patients who meet the inclusion criteria are randomly divided into two groups of intervention and control after obtaining informed consent. In the intervention group, patients will cycle for 6 months, at least 3 times a week, for 30 minutes during the first 2 hours of dialysis, so that the first 5 minutes are for warming up, 20 minutes for maximal activity, and the last 5 minutes for cooling down. Bikes are portable and will be fixed to the bed. Vital signs of patients will be examined and charted at least 3 times per session.

Category

Other

2

Description

Control group: Patients undergoing hemodialysis treatment with at least 6 months of hemodialysis history,

who are eligible but reluctant to enter the study are registered in the plan. Patients will undergo routine hemodialysis for the next 6 months, at least 3 times a week for 4 hours.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzdarman Hemodialysis Clinic

Full name of responsible person

Dr. Hamid Taravati

Street address

n. 130, Kolehdoz 18 Ave., Kolehdoz Blvd, Mashhad

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htaravati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

Mashhad University of Medical Sciences

Proportion provided by this source

23

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

2**Sponsor****Name of organization / entity**

SabzDarman Clinic

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

SabzDarman Clinic

Proportion provided by this source

77

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Arash Sefidgaran

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Maryam Hami

Position

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Latest degree

Subspecialist

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Dr. Arash Sefidgaran

Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

The data can be used to research and provide new solutions by citing the source.

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