Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

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+98 51 1765 9556

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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 fraction Poor control diabetes mellitus Intake of immunosuppressant drugs tempreture>38' Hemodynamic disorders Cerebrovascular disease Active lung disease CardiacEjection 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.
City
Mashhad
Province
Razavi Khorasan
Postal code
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 adequecy 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, Kolahdouz 18 Ave., Kolahdouz Blvd, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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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
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Dr. Arash Sefidgaran
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Person responsible for updating data

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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