Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intradialysis exercise in quality of life and time of recovery in patients on hemodialysis

Protocol summary

Study aim
Determination and comparison of intradialysis exercise on quality of life and recovery time of hemodialysis patients

Design
A non blinded, parallel group , randomized with random number, controlled clinical trial with a parallel group design of 58 patients between November 2019 and February 2020

Settings and conduct
58 hemodialysis patients in Alzahra & Khorshid hospitals work with Minibike in second hour of dialysis for 30 minutes after training. Before study and after 3 months of study, quality of life questioner and recovery time is filled. Iron storage values, lipid profile and albumin are measured in beginning and after completion of study. in control group, questionnaire and laboratory values are filled.

Participants/Inclusion and exclusion criteria
At least 3 months hemodialysis patients that agree to participate to cooperation with absence of chest pain, systemic blood pressure less than 180/110 mmHg . absence of vascular complications, absence of distal vascular access arrived in study. If they have dyspnea or fever more than 38 degree or chest pain during hemodialysis are excluded.

Intervention groups
Study group: exercise during second hours of dialysis with minibike for 30 minute Control group: without exercise

Main outcome variables
quality of life score؛ recovery time؛ Iron storage changes؛ lipid profile changes؛ albumin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090905002417N22**
Registration date: **2019-11-25, 1398/09/04**
Registration timing: **prospective**

Last update: **2019-11-25, 1398/09/04**
Update count: **0**

Registration date
2019-11-25, 1398/09/04

Registrant information

Name
Firouzeh Moeinzadeh

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-05-20, 1399/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of intradialysis exercise in quality of life and time of recovery in patients on hemodialysis

Public title

the effect of intradialysis exercise on hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodialysis at least 3 months Interesting to study cooperation Has not amputation in lower limb Has not musculoskletal problems like rheumatologic disorders, limb trauma

Exclusion criteria:

Systemic blood pressure more than 180/110 Presence of chest pain Dyspnea during hemodialysis Fever more than 38 degree during hemodialysis Lower limb vascular access

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, individual with random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences

Street address

Hezar jarib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-10-15, 1398/07/23

Ethics committee reference number

IR.MUI.MED.REC.1398.368

Health conditions studied

1

Description of health condition studied

Effect of intradialysis exercise on quality of life and recovery time

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Quality of life score

Timepoint

Before exercise and 3 months after

Method of measurement

SF-KDQOL questioner

2

Description

Recovery time

Timepoint

Before exercise and 3 months later

Method of measurement

Question

Secondary outcomes

1

Description

Serum iron level

Timepoint

Before exercise and 3 months later

Method of measurement

Laboratory kit ELISA

2

Description

Ferritin

Timepoint

Before and 3 months later

Method of measurement

Laboratory kit ELISA

3

Description

Total iron binding capacity

Timepoint

Before exercise and 3 months later

Method of measurement

Laboratory kit ELISA

4

Description
Triglyceride
Timepoint
Before exercise and 3 months later
Method of measurement
Laboratory kit ELISA

5

Description
Total cholesterol
Timepoint
Before exercise and 3 months later
Method of measurement
Laboratory kit ELISA

6

Description
Albumin
Timepoint
Before exercise and 3 months later
Method of measurement
Laboratory kit ELISA

Intervention groups

1

Description
Intervention group: intradialysis exercise in second hour of dialysis for half of hour via Minibike manufactured by Taiwan
Category
Treatment - Devices

2

Description
Control group: hemodialysis patients without exercise
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Safoura Shahzeidi
Street address
Sofe street
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2

Recruitment center
Name of recruitment center
Khorshid hospital
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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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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
Dr Firouzeh Moeinzadeh
Position
Assistant Professor of Nephrology
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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
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
Results of study would be available
When the data will become available and for how long
After October 2020
To whom data/document is available
Only academic institutes permit for results
Under which criteria data/document could be used
Medical Students permit
From where data/document is obtainable
via f_moinzade@med.mui.ac.ir
What processes are involved for a request to access data/document
It will response during 1 month after receiving email
Comments