

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 5555

Email address

moinzade@resident.mui.ac.ir

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 musculoskeletal 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

Isfahan

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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81764675731

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2

Recruitment center**Name of recruitment center**

Khorshid hospital

Full name of responsible person

Safoura Shahzeidi

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8135673381

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjooy Javanmard

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Hezar Jarib Avenue

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research@mui.ac.ir

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**

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

Latest degree
Subspecialist

Other areas of specialty/work
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