

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effect exercise during hemodialysis on blood level of Parathyroid hormone, Calcium, Phosphate and Albumin patients undergoing hemodialysis

#### Protocol summary

##### Study aim

The effect of exercise during dialysis on the blood levels of Parathyroid hormone, Calcium, Phosphorus, Albumin of patients undergoing hemodialysis

##### Design

A controlled clinical trial with a parallel group design of 60 patients

##### Settings and conduct

Study setting: hemodialysis ward of Alzahra Hospital belonging to Isfahan University of Medical Sciences. How to do the study: Patients will be divided into two groups of intervention and control. The intervention group will exercise for 30 minutes. Blood samples are given and sent to the laboratory. The control group will receive simple exercise. This work will be done for 8 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 65 years old; having full consciousness and being able to listen and speak to answer to questions; history of hemodialysis more than 3 months; having 3 dialysis sessions per week. Exclusion criteria: physical and mental disability; known ischemic heart disease, heart attacks and angina during the last three months; suffering from acute pulmonary disease and needing for oxygen during hemodialysis; history of stroke or ischemic attacks over the last 3 months; suffering from muscle disorders that prevent intended exercise; history of parathyroidectomy.

##### Intervention groups

Intervention group: this group will participate in an exercise program. In this program, they will exercise in 2 courses (30 minute) and between these courses, the patient will rest for 30 minutes. This exercise is done for 8 weeks, three times a week.

##### Main outcome variables

The levels of Parathyroid hormone; Calcium; Phosphorus; Albumin of blood

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150116020675N4**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

##### Registration date

2020-09-01, 1399/06/11

##### Registrant information

##### Name

Alireza Dashti

##### Name of organization / entity

Alzahra Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3620 1322

##### Email address

alireza\_dashti@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effect exercise during hemodialysis on blood level of Parathyroid hormone, Calcium, Phosphate and Albumin patients undergoing hemodialysis

### Public title

Effect exercise during hemodialysis on blood level of Parathyroid hormone, Calcium, Phosphate and Albumin patients undergoing hemodialysis

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age between 18 and 65 years old Having full consciousness and being able to listen and speak to answer to questions History of hemodialysis at least 3 months Not having cardiac ischemia, MI and Cardiac angina over last three months Not having severe pulmonary disease Not having history of CVA or ischemic attack over last three months Not having any skeletal muscular disease that prevents patients from doing exercise The patients are treated with hemodialysis three times a week (4 hours) Not having history of parathyroidectomy surgery Not having physical and mental disability

#### Exclusion criteria:

Not having tendency to continue participating in the study in any stage of the study Suffering from cardiovascular, pulmonary diseases and any disorder that prevents the patient from doing exercise during the study. Not doing exercise for two consecutive sessions or four non-consecutive sessions

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The patients participating in the study are divided into groups (intervention and control) by simple random allocation method and using a package containing even and odd numbers.

### 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 School of Medicine - Isfahan University of Medical Sciences

##### Street address

Hezarjarib Ave.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746734461

#### Approval date

2020-06-07, 1399/03/18

#### Ethics committee reference number

IR.MUI.MED.REC.1399.212

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney disease

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

The level of parathyroid hormone in blood

#### Timepoint

At the beginning of the study and 8 weeks after the beginning of the intervention

#### Method of measurement

Blood Test

## Secondary outcomes

### 1

#### Description

The levels of Calcium of blood

#### Timepoint

At the beginning of the study and 8 weeks after the beginning of the intervention

#### Method of measurement

Blood test

## 2

### **Description**

The level of phosphorus of blood

### **Timepoint**

At the beginning of the study and 8 weeks after the beginning of the intervention

### **Method of measurement**

Blood test

## 3

### **Description**

The level of Albumin of blood

### **Timepoint**

At the beginning of the study and 8 weeks after the beginning of the intervention

### **Method of measurement**

Blood test

## **Intervention groups**

### 1

#### **Description**

Intervention group: the group will participate in a exercise program. In this program, they will exercise in 2 courses (30 minute) and between these courses, the patient will rest for 30 minute. This exercise is done by fixed bike. The intensity of the exercise will depend on the machine rotation round and is selected by patient. This exercise is done for 8 weeks , three times a week.

#### **Category**

Other

### 2

#### **Description**

Control group: this group will participate in a exercise program include calisthenics exercises which lasts for 10 minute, 8 weeks and three times in the week.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra Hospital

##### **Full name of responsible person**

Alireza Dashti dehkordi

##### **Street address**

Soffeh Ave.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174675731

##### **Phone**

+98 31 3822 2268

##### **Email**

alireza\_dashti@nm.mui.ac.ir

##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Shaghayegh Haghjoo javanmard

##### **Street address**

Hezargarib Ave.

##### **City**

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##### **Province**

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##### **Postal code**

7346181746

##### **Phone**

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##### **Email**

sh\_haghjoo@med.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**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Alireza Dashti dehkordi

##### **Position**

Nurse

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

##### **Street address**

Soffeh Ave.

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Nahid Shahgholian

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Dashti dehkordi

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Soffeh Ave..

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3822 2268

**Email**

alireza\_dashti@nm.mui.ac.ir

**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