

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis

##### Design

This is a randomized clinical trial with a control group with parallel groups without blinding, in which 40 eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

##### Settings and conduct

This study will be conducted at the Beheshti Hospital in Hamadan city, involving 40 eligible patients undergoing hemodialysis. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not feasible in this trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Patients undergoing hemodialysis, Exclusion criteria: Movement disorders

##### Intervention groups

Intervention group: Treatment and routine care for hemodialysis patients, along with aerobic exercises including pedaling on a stationary mini electric bike for 30 minutes, and resistance exercises including leg raises (two sets of 10 repetitions), heel raises (three sets of 15 repetitions), and knee flexion and extension (two sets of 10 repetitions), performed three days per week for three months. Control group: Treatment and routine care for hemodialysis patients

##### Main outcome variables

Primary outcome: Blood calcium level; Blood phosphorus level; Blood sodium level; Blood potassium level; Blood hemoglobin level; Blood hematocrit level; Blood platelet level; Blood creatinine level; Blood urea level; Blood albumin level; Blood triglyceride level; Blood alkaline phosphatase level; Blood SGOT level; Blood SGPT level; Blood parathyroid hormone level; Psychological

symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N608**

Registration date: **2026-05-14, 1405/02/24**

Registration timing: **prospective**

Last update: **2026-05-14, 1405/02/24**

Update count: **0**

##### Registration date

2026-05-14, 1405/02/24

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2026-05-31, 1405/03/10

##### Expected recruitment end date

2026-09-01, 1405/06/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis: a randomized clinical trial

**Public title**

Effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 65 years, Patients undergoing hemodialysis,

**Exclusion criteria:**

Movement disorders

**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: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.

**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 Islamic Azad University - Boroujerd Branch

**Street address**

Islamic Azad University, Boroujerd Branch, Navab Square

**City**

Boroujerd

**Province**

Lorestan

**Postal code**

6915136111

**Approval date**

2026-04-22, 1405/02/02

**Ethics committee reference number**

IR.IAU.B.REC.1405.018

**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

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

Blood calcium level

**Timepoint**

Before the intervention and three months later

**Method of measurement**

By taking and testing a blood sample

**2****Description**

Blood phosphorus level

**Timepoint**

Before the intervention and three months later

**Method of measurement**

By taking and testing a blood sample

**3****Description**

Blood sodium level

**Timepoint**

Before the intervention and three months later

**Method of measurement**

By taking and testing a blood sample

**4****Description**

Blood potassium level

**Timepoint**

Before the intervention and three months later

**Method of measurement**

By taking and testing a blood sample

## 5

### **Description**

Blood hemoglobin level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 6

### **Description**

Blood hematocrit level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 7

### **Description**

Blood platelet level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 8

### **Description**

Blood creatinine level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 9

### **Description**

Blood urea level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 10

### **Description**

Blood albumin level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 11

### **Description**

Blood triglyceride level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 12

### **Description**

Blood cholesterol level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 13

### **Description**

Blood alkaline phosphatase level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 14

### **Description**

Blood SGOT level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 15

### **Description**

Blood SGPT level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 16

### **Description**

Blood parathyroid hormone level

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

By taking and testing a blood sample

## 17

### **Description**

Psychological symptoms

### **Timepoint**

Before the intervention and three months later

### **Method of measurement**

Using the Garnefski standard questionnaire.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Treatment and routine care for

hemodialysis patients, along with aerobic exercises including pedaling on a stationary mini electric bike for 30 minutes, and resistance exercises including leg raises (two sets of 10 repetitions), heel raises (three sets of 15 repetitions), and knee flexion and extension (two sets of 10 repetitions), performed three days per week for three months.

**Category**

Other

**2****Description**

Control group: Treatment and routine care for hemodialysis patients

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Beheshti Hospital in Hamadan city

**Full name of responsible person**

Fahimeh Ghodrati

**Street address**

Beheshti Hospital, Eram Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0283

**Email**

fahimeghorati@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Ali Aryapoor

**Street address**

Islamic Azad University, Borujerd Branch, Navab Square

**City**

Borujerd

**Province**

Lorestan

**Postal code**

6915136111

**Phone**

+98 66 4251 8000

**Email**

info.research@IAU.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Fahimeh Ghodrati

**Position**

Student of Exercise Physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

**Street address**

Islamic Azad University, Borujerd Branch, Navab Square,

**City**

Borujerd

**Province**

Lorestan

**Postal code**

6915136111

**Phone**

+98 66 4251 8000

**Email**

fahimeghorati@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Dr. Mehdi Roozbahani

**Position**

Specialist in Exercise Physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

**Street address**

Islamic Azad University, Borujerd Branch, Navab

Square,  
**City**  
Boroujerd  
**Province**  
Lorestan  
**Postal code**  
6915136111  
**Phone**  
+98 66 4251 8000  
**Email**  
mehdi.roozbahani@iau.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Jalal Poorolajal  
**Position**  
Professor of Epidemiology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
**Street address**  
School of Public Health, Hamadan University of  
Medical Sciences, Fahmideh Ave  
**City**  
Hamadan  
**Province**

Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0090  
**Email**  
poorolajal@umsha.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