

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of aerobic training during haemodialysis on sleep quality and systemic inflammation in haemodialysis patients

#### Protocol summary

##### Summary

The objective of this study is to assess the effect of intradialytic aerobic training on sleep quality and systemic inflammation in haemodialysis patients. Twenty haemodialysis patients will participate in the study. The patients will be randomly assigned to aerobic intervention or control group. The intervention group will participate in an 8-week aerobic training during dialysis (three times a week, 60 min/session). The intensity of the exercise program is condition level 12-16 according to the rate of perceived exertion (RPE), moderate intensity. Sleep quality [the Pittsburgh sleep quality index (PSQI)], C-reactive protein (systemic inflammatory index), and cardiorespiratory fitness will be measured prior to and after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138812023387N1**

Registration date: **2010-07-11, 1389/04/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-07-11, 1389/04/20

##### Registrant information

###### Name

Abbas Saremi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1277 7400

##### Email address

a-saremi@araku.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University

##### Expected recruitment start date

2010-07-11, 1389/04/20

##### Expected recruitment end date

2010-08-11, 1389/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of aerobic training during haemodialysis on sleep quality and systemic inflammation in haemodialysis patients

##### Public title

Effects of aerobic training during haemodialysis on sleep quality and systemic inflammation in haemodialysis patients

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: receiving maintenance haemodialysis more than 6 months, age more than 20 years, having bad sleep quality, providing informed consent Exclusion criteria: use of immunosuppressant, immunomodulators or steroid that may influence serum cytokines levels, presence of heart failure or active infection, presence of depressive disorder

##### Age

From **20 years** old to **60 years** old

##### Gender

Male

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Arak University

##### Street address

Arak University, Arak, Iran

##### City

Arak

##### Postal code

009886138156

#### Approval date

2010-04-07, 1389/01/18

#### Ethics committee reference number

19207/87/3

## Health conditions studied

### 1

#### Description of health condition studied

haemodialysis patients

#### ICD-10 code

E85.3

#### ICD-10 code description

Secondary systemic amyloidosis

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

before and after 8 weeks intervention

#### Method of measurement

Pittsburgh sleep quality questionnaire

### 2

#### Description

C reactive protein

#### Timepoint

before and after 8 weeks intervention

#### Method of measurement

ELISA method, mg/l

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

8 weeks exercise training, 3 session per week, moderate intensity

#### Category

Rehabilitation

### 2

#### Description

Routine lifestyle

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghiasi Hospital

##### Full name of responsible person

Dr Abbas Saremi

##### Street address

Iran, Arak, Arak University

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University

##### Full name of responsible person

Dr Shavandi

##### Street address

Arak University, Iran

##### City

Arak

#### Grant name

25

#### Grant code / Reference number

12/45/4782

#### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

Arak University

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

Arak University

**Full name of responsible person**

Dr Abbas Saremi

**Position**

Exercise physiologist

**Other areas of specialty/work****Street address**

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**Email**

a-saremi@araku.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*