

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

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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

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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