Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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/د

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 quesrionnaire

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
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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

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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