Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cimbination of exercise and curcumin supplementation on serum ferritin and serum albumin in hemodialysis patients

Protocol summary

Study aim
Studying the effect of 12 weeks of combined exercises and curcumin consumption on serum ferritin and serum albumin in hemodialysis (HD) patients

Design
A clinical trial with a control group with parallel groups without blinding and randomized with a table of random numbers with 80 patients.

Settings and conduct
In this research, the subjects are selected from HD patients after being called and invited to participate in Khurshid HD Center of Isfahan according to the criteria for entering with the approval of specialist doctors and then they sign informed consent. They will be randomly assigned to one of the four groups, exercise group, supplement group, exercise and supplement group and control. will be placed. The intervention includes 12 weeks of combined exercises, which each week includes 3 exercise sessions for 45 minutes and 12 weeks of taking 2 curcumin supplements daily after the main meal.

Participants/Inclusion and exclusion criteria
Inclusion criteria:undergoing HD for at least 1, having inflammation and agreeing to participate, exclusion criteria: having medical contraindications for exercise and taking curcumin

Intervention groups
Intervention group (IG)1: Training group performing exercise for 12 weeks; 3 sessions weekly, each for 45 minutes. Exercise training consists of 3 bouts of resistance with 12 repetitions, and 3 bouts of aerobic exercise with 15 repetitions. IG 2: supplemented with curcumin capsules, taking 2 capsules daily (equivalent to 1000 ml grams of curcumin (preferably to be consumed after the main meal). IG3: exercise and supplement consumption group, who performed the same exercise protocol as the exercise group and in addition, consumed 1000 mg of curcumin supplement daily for 12 weeks. Control group: They did not have any sports activities and supplement consumption.

Main outcome variables
Serum ferritin, serum albumin, 6-minute walking test

General information

Reason for update
End of recruitment

Acronym

IRCT registration information
IRCT registration number: **IRCT20200819048461N2**
Registration date: **2022-12-21, 1401/09/30**
Registration timing: **prospective**

Last update: **2023-02-16, 1401/11/27**
Update count: **1**

Registration date
2022-12-21, 1401/09/30

Registrant information

Name
Mohammad ali Tabibi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-03, 1401/10/13

Expected recruitment end date
2023-01-24, 1401/11/04

Actual recruitment start date
2023-01-08, 1401/10/18

Actual recruitment end date
2023-01-31, 1401/11/11
Trial completion date
empty

Scientific title
The effect of cimbination of exercise and curcumin supplementation on serum ferritin and serum albumin in hemodialysis patients

Public title
The effect of exercise and curcumin on hemodialysis disease
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 80 years More than three months of dialysis experience Having a three-time hemodialysis program No heart attack and stroke in the past three months Having the ability to communicate with others The permission of the attending physician to practice be clinically stable
Exclusion criteria:
Unstable heart condition (angina, congestive heart failure, severe arterial stenosis, uncontrolled arrhythmias, etc.) Active infection or acute medical illness Hemodynamic instability, unstable blood sugar unable to exercise (lower limb amputation without prosthesis) Having severe skeletal-muscular pain at rest or minimal activity Having shortness of breath while resting or with daily activities Allergy or insensitivity to turmeric
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
En Simple randomization, individual with random number generation program Randomization was performed by a biostatistician using a computer-generated randomization program [using Stata 16, StataCrop, College Station, Tx] with an allocation ratio of 1:1. For allocation concealment, allocation information will be protected in opaque sealed envelopes by an identified individual not participating in the study. Only after participant registration and baseline measurements are completed will envelopes be opened.
Blinding (investigator's opinion)
Single blinded
Blinding description
One of the experimental groups of the research was the exercise + supplement group, which received the supplement in the form of capsules along with doing sports exercises, and the second experimental group was the exercise group, which only exercised and a capsule that looked similar to the supplement capsule but contained He was receiving curcumin.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee
Street address
J Sharghi St., Arghavanieh
City
Esfahan
Province
Isfehan
Postal code
81551-39998
Approval date
2022-09-05, 1401/06/14
Ethics committee reference number
IR.IAU.KHUISF.REC.1401.168

Health conditions studied

1

Description of health condition studied
End stage renal disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
The normal level of ferritin in serum is between 10 and 300 nanograms per milliliter, and ferritin levels above 200 nanograms per milliliter in women and above 300 nanograms per milliliter in men have been diagnosed as abnormal. Serum ferritin levels in hemodialysis patients measurement of serum ferritin in the bloodstream can be useful for monitoring the progress of hemodialysis disease.

Timepoint

Ferritin measurement of the subjects' blood was done in two stages, the first stage in the initial blood sampling, i.e. 24 hours before the start of the exercise protocol and curcumin supplementation, and the second stage in the blood sample of the last stage, three months after the last exercise session and the last curcumin intake a done.

Method of measurement

To measure serum ferritin, it was measured and recorded using the ARKA kit by ELISA method (Enzyme-linked immunoadsorbent assay).

2

Description

Serum albumin level, the normal level of serum albumin is between 4.3 and 4.5 grams per deciliter, and hemodialysis patients have low albumin levels. Measuring the amount of serum albumin in the bloodstream can be useful for monitoring the progress of hemodialysis patients.

Timepoint

Measuring the blood albumin of the subjects in two stages, the first stage in the initial blood sampling, i.e. 24 hours before the start of the exercise protocol and taking curcumin supplement and the second stage, in the final stage blood sampling, three months after the last session of sports training and the last curcumin intake a done .

Method of measurement

The amount of albumin was measured and recorded by the Bionik laboratory kit, using the autoanalyzer olympus model AU made in Iran.

Secondary outcomes

1

Description

Functional status

Timepoint

Before starting exercise and taking curcumin and three months later

Method of measurement

6-minute walking test

Intervention groups

1

Description

The first intervention group :the experimental group will do 3 sessions of 45-minute exercise program per week at home on non-dialysis days with the simultaneous supervision of an online trainer for 12 weeks. These exercises are taught face-to-face in the first week. resistance exercises (2 sets of 12 repetitions, including anterior and posterior knee strengthening, lateral hip joint strengthening (adductors and abductors), strengthening of the anterior and posterior leg system, rest period between sets 30 to 60 secondsconsidered) aerobic exercise (3 turns of 15 repetitions of walking backwards, walking and turning, walking sideways, stopping on heels and toes, walking on heels and toes and walking on stairs). It is worth mentioning that before and after each training session, the subjects performed static stretching and softening movements to warm up and cool down the body.

Category

Treatment - Other

2

Description

The second intervention group :The experimental group will receive curcumin supplements in the form of capsules for 12 weeks, in such a way that these capsules will be delivered to them once every 3 weeks. All capsules will be the same in terms of shape, quantity, size, and color.Theparticipants will be asked to take 2 capsules of curcumin daily (equivalent to 1000 mg of curcumin) preferably after the main meal.

Category

Placebo

3

Description

The third intervention group : the exercise group was +supplement. The subjects in this group, along with the exercise group, performed combined exercises, and during the research period, they received 1000 mg of curcumin supplement (manufactured by Dineh company) daily for 12 weeks.

Category

Treatment - Other

4

Description

Control group: Subjects in this group did not do any exercise during the research period (12 weeks) and did not receive any supplements

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Shahrazad Shahidi

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ostandari Street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University of Khorasgan, Isfahan
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
Mehsa Soleimani Sadeh
Position
Master's degree
Latest degree
Master
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the study group are made available
When the data will become available and for how long
After october 2023
To whom data/document is available
Only academics are allowed
Under which criteria data/document could be used
If the data is used for the purpose of research in the field of variables and providing new solutions, it can be used by mentioning the source
From where data/document is obtainable
by email m.tabibi@ut.ac.ir
What processes are involved for a request to access data/document
It will be answered within one month after receiving the email
Comments