Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Interactive effect of ISO protein consumption and eight weeks of combined training during dialysis on serum levels of hepcidin , interleukin-6, iron , ferritin and renal function indices, body fat percentage, lipid profile, glycemic index and MIS and DMS scale in hemodialysis patients

Protocol summary

Study aim

Determining the interactive effect of ISO protein consumption and eight weeks of combined training during dialysis on serum levels of hepcidin, interleukin-6, iron, ferritin, renal function, glycemic index, lipid profile, body fat percentage and malnutrition scale in hemodialysis patients

Design

A clinical trial with a control group with parallel, non-blind, simple random groups will be performed on 30 dialysis patients.

Settings and conduct

All patients undergoing hemodialysis referred to the special diseases clinic of Imam Khomeini Hospital in Zabol city The statistical population of the present study is that from all patients referred to the clinic 30 patients (male and female) undergoing hemodialysis in the age range of 25-55 years. Targeted form will be selected and will be randomly divided into 3 groups including 10 in the control group, 10 in the combined training group and 10 in the combined training + supplement group.

Participants/Inclusion and exclusion criteria

Hemodialysis 3 times a week, age range 25-55 years Body mass index 35-18.5 kg / m2, at least 6 months of hemodialysis treatment, no severe respiratory and heart failure, chronic inflammatory disease of unknown origin, dementia, Cancer, hepatitis B, C, no use of oral supplements and intravenous nutrition Neurological disease and recent surgical history in the last quarter

Intervention groups

In the training group, combined exercises including aerobics and endurance will be performed for eight weeks In the supplement-exercise group, in addition to eight weeks of combined exercise, subjects will be given an ISO protein supplement, and the control group will not undergo any intervention during the study.

Main outcome variables

Serum levels of hepcidin, interleukin-6, iron, ferritin, renal function, glycemic index, lipid profile, body fat percentage and malnutrition scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220121053779N1**
Registration date: **2022-03-05, 1400/12/14**
Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**
Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

elham sargol hossein zadeh

Name of organization / entity

The University of Sistan and Balouchestan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-03-15, 1400/12/24
Expected recruitment end date
2022-05-14, 1401/02/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Interactive effect of ISO protein consumption and eight weeks of combined training during dialysis on serum levels of hepcidin , interleukin-6, iron , ferritin and renal function indices, body fat percentage, lipid profile, glycemic index and MIS and DMS scale in hemodialysis patients

Public title
Evaluation of the effect of combination training and ISO supplementation in dialysis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Hemodialysis 3 times a week Body mass index 35-18/5 kg / m2, At least 6 months on hemodialysis treatment, Absence of severe respiratory and heart failure, chronic inflammatory disease of unknown origin, dementia, cancer, hepatitis B, C, neurological disease, HIV Do not use oral supplements and intravenous nutrition No history of recent surgery in the last quarter Range age 25-55 years
Exclusion criteria:
Lack of cooperation of the patient to implement the research protocol, including failure to perform at least two sessions of exercise or lack of supplementation by the patient
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random - After selecting the patients who met the age and inclusion criteria, the three groups will be selected by lot in a homogeneous manner. For each group, an equal number of men and women were selected by lot, then based on the age of the people Ages 25-35 years old were written on paper and were selected by lot for each group, then in the age range 35-55 years old, they were homogenized in the same way.
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 Sistan and Baluchestan University
Street address
Zahedan, Daneshjoo St. Daneshjoo 76
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9861913113
Approval date
2022-01-12, 1400/10/22
Ethics committee reference number
IR.USB.REC.1400.078

Health conditions studied

1

Description of health condition studied
Chronic kidney disease
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Serum levels of interleukin-6
Timepoint
Measurement of interleukin-6 levels at the beginning of the study and after 8 weeks of protocol implementation
Method of measurement
Using blood samples with ELISA technique

2

Description
Serum levels of hepcidin
Timepoint

Measurement of hepcidin levels at the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using blood samples with ELISA technique

3

Description

Glycemic indexes include fasting blood sugar, insulin and insulin resistance

Timepoint

Measurement at the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using blood samples with ELISA technique

4

Description

Lipid profile

Timepoint

Measurement at the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using blood samples with ELISA technique

5

Description

Kidney function indicators

Timepoint

Measurement at the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using blood samples with ELISA technique

6

Description

Serum iron levels

Timepoint

Measurement at the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using blood samples with ELISA technique

7

Description

Serum ferritin level

Timepoint

Measurement at the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using blood samples with ELISA technique

8

Description

The rate of malnutrition

Timepoint

At the beginning of the study and after 8 weeks of protocol implementation

Method of measurement

Using the Malnutrition-Inflammation Questionnaire

9

Description

Percentage of body fat

Timepoint

At the beginning of the study and after the end of the study

Method of measurement

Using a caliper

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the supplement-activity group, the subjects were trained for 8 weeks at the end of each dialysis session (3 sessions per week). Or 24 grams in 150 cc of water will be consumed after each dialysis session

Category

Treatment - Other

2

Description

Intervention group: In the experimental group, the program will perform combined exercises during dialysis, three sessions per week for 8 weeks. The combined training program will include two parts, aerobic training and resistance training, and each training session will include four stages of warm-up, aerobic training, resistance training and cooling phase. The warm-up phase also includes: lower extremity stretching exercises and cycling activity at 30% of the maximum heart rate for five minutes. Will do. These exercises start with the lowest intensity (50 to 60% of maximum heart rate) and short duration (10 to 20 minutes) and gradually increase in intensity and duration of exercise in each session. Also, because in these special patients due to dialysis conditions, heart rate responses and blood pressure to exercise are different, the Borg scale is used to determine the intensity of exercise and the progress in intensity and duration of exercise is determined based on patients' perception of exercise pressure. According to the Borg Scale, the training pressure in the first month with the perceived effort (RPE) will be nine to 11, and in the last month the work intensity will reach 12 to 14 RPE. Also, resistance exercises will be performed using resistance bands. These exercises include: movements of opening the knee, bending the thigh, moving the thigh and raising the thigh in a straight position. Each movement will be done once or twice in the first month, two to three times in the second month with 12 to 15 repetitions. The amount of overload for each patient will be done separately by changing the colorant. During

both aerobic and resistance training, every five minutes the patient is asked to rate his or her workout pressure and fatigue at that point based on a 20-point Borg pressure scale. In addition, the cooling phase will include two minutes of pedaling at 30% of maximum heart rate and inactive lower limb traction.

Category
Rehabilitation

3

Description
Control group: Control group: In the control group, no training and complementary interventions will be performed

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Special Diseases Center of Imam Khomeini Hospital in Zabol

Full name of responsible person
Elham sargol hossein zadeh

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No. 1, Bagheri 22 ., corner of the alley, Bagheri Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Sistan and Baluchestan

Full name of responsible person
Hamed Quhani Arab

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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
Faculty of Sports Sciences

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
The University of Sistan and Baluchestan

Full name of responsible person
Elham Sargol Hossein Zadeh

Position
Masters Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Position
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Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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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
Some of the required data such as subjects' background information as well as some of the outcome data can be shared.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic, scientific and industrial institutes

Under which criteria data/document could be used
The published results are unobstructed in case of documented use in scientific articles by mentioning the title and also for justification plans.

From where data/document is obtainable
By e-mail elhamhosseinzadeh22@gmail.com

What processes are involved for a request to access data/document
The applicant must state clear and documented reasons for the use of the data by e-mail. After the necessary checks, the data will be provided to the researcher up to one month after the request.

Comments