Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The effect of 8 weeks of aerobic exercise with propolis supplementation on biomarkers of oxidative stress in hemodialysis patients

Protocol summary

Study aim

The purpose of this study was to determine the effect of 8 weeks of aerobic exercise with propolis supplementation on biomarkers of oxidative stress in hemodialysis patients

Design

A randomized, double-blind randomized controlled trial with a sample size of 60 patients

Settings and conduct

In this study, 60 adult patients aged 30 to 65 years with renal failure undergoing hemodialysis at Ale Muhammad Medical polyclinic and Emergency service in Mashhad, were selected based on inclusion criteria and randomly divided into four groups of study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. An age range of 18 to 65 years; 2. ESRD patients on hemodialysis treatment; 3. Perform hemodialysis 3 days a week; 4. Willingness to participate in research. Exclusion criteria: 1. BMI above 30 kg/m; 2. Having diseases such as gallstones, cancer, and acute diseases; 3. Acute heart accident in the past year; 4. Taking any medicine outside the routine treatment protocol of hemodialysis patients; 5. Any allergy to honey and its compounds; 6. Smoking, drug addiction or alcohol consumption

Intervention groups

Four groups of intervention and control; the first group received 500 mg of propolis per day, 2 capsules containing 250 mg Propolis extract with 3 days a week exercise program with a stationary bike, the second group received 500 mg of propolis per day, 2 capsules containing 250 mg Propolis extract, the third group received 500 mg of placebo per day, 2 capsules containing 250 mg placebo with 3 days a week exercise program with a stationary bike, the fourth group received 500 mg of placebo per day, 2 capsules containing 250 mg placebo extract for 8 weeks.

Main outcome variables

Malondialdehyde; Total antioxidant capacity; Systolic and diastolic pressure; Nutritional status; Anthropometric indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220102053595N1**
Registration date: **2022-02-17, 1400/11/28**
Registration timing: **prospective**

Last update: **2022-02-17, 1400/11/28**
Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Sina Hamidi pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3876 5642

Email address

hamidipour.sina.nu@mshdiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-04-16, 1401/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of 8 weeks of aerobic exercise with propolis supplementation on biomarkers of oxidative stress in hemodialysis patients

Public title
The effect of propolis supplementation in hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
An age range of 18 to 65 years ESRD patients on hemodialysis treatment Perform hemodialysis 3 days a week Absence of any physical abnormalities or bone diseases that interfere with their physical activity Willingness to participate in research

Exclusion criteria:
BMI above 30 kg/m Disease (gallstones, cancer, and acute disease) Acute heart accident in the past year Taking any medicine outside the routine treatment protocol of hemodialysis patients Use of oral and injectable nutritional supplements except nephrovit and iron supplements according to the protocol Any allergy to honey and its compounds Leaving the patient with his/her personal consent Smoking, drug addiction or alcohol consumption

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the patients with renal failure undergoing hemodialysis referred to Ale Muhammad Medical polyclinic and Emergency service in Mashhad, 60 patients will be selected based on inclusion criteria and personal satisfaction and will be matched according to age and gender, then randomly assigned to one of four intervention and control groups. Patients will be randomly divided into intervention and control groups using statistical software and block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
The capsules are standardized in all groups in terms of appearance, color, and odor. From the selection of the person, no one will be aware of the type of treatment he/she will receive. Finally, data and information are given to the statistician with a special code for each group, so that the statistician can also be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Islamic Azad University- Mashhad Branch

Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
9164697515

Approval date
2022-01-19, 1400/10/29

Ethics committee reference number
IR.IAU.MSHD.REC.1400.134

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
Malondialdehyde

Timepoint
At the beginning and end of the study

Method of measurement
kit

2

Description
Total antioxidant capacity

Timepoint
At the beginning and end of the study

Method of measurement
kit

3

Description
Systolic blood pressure
Timepoint
At the beginning and end of the study
Method of measurement
Mercury manometers

4

Description
Diastolic blood pressure
Timepoint
At the beginning and end of the study
Method of measurement
Mercury manometers

5

Description
Nutritional status
Timepoint
At the beginning and end of the study
Method of measurement
Food recall and 3-day food record questionnaires

6

Description
Anthropometric indicators
Timepoint
At the beginning and end of the study
Method of measurement
Weighing scale, Tape measure, BIA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the first group received 500 mg of propolis per day, 2 capsules containing 250 mg Propolis extract, 1 capsule before lunch, and 1 capsule before dinner, with 3 days a week exercise program with a stationary bike according to the protocol for 8 weeks. Propolis capsules have been prepared by Shahdineh Golha Honey Company located in Najafabad, Isfahan, and propolis extract has been extracted alcoholically.
Category
Treatment - Drugs

2

Description
Intervention group: the second group received 500 mg of propolis per day, 2 capsules containing 250 mg Propolis extract, 1 capsule before lunch, and 1 capsule before dinner, without exercise for 8 weeks. Propolis capsules have been prepared by Shahdineh Golha Honey Company located in Najafabad, Isfahan, and propolis extract has been extracted alcoholically.
Category
Treatment - Drugs

3

Description
Control group: the third group received 500 mg of placebo per day, 2capsules containing 250 mg placebo, 1 capsule before lunch, and 1 capsule before dinner, with 3 days a week exercise program with stationary bike according to the protocol for 8 weeks
Category
Placebo

4

Description
Control group: the fourth group received 500 mg of placebo per day, 2 capsules containing 250 mg placebo extract, 1 capsule before lunch, and 1 capsule before dinner, without exercise for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ale Muhammad Medical polyclinic and Emergency service
Full name of responsible person
Dr.Mohammad reza Maleki
Street address
Imam Reza St, Chahar Rah Danesh, Shahid Hanaei 19
City
Mashhad
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Razavi Khorasan
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9187147578
Phone
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Email
alenabiclinic@gmail.com
Web page address
http://almohamad.com/en/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zohre Amir khani
Street address

Ostad Yusofi Street, Emamieh Boulevard ,GhasemAbad

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sahar56h@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Personal financial source

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Sina Hamidi pour

Position
Postgraduate student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Ostad Yusofi Street, Emamieh Boulevard ,GhasemAbad, Mashhad, Iran.

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Person responsible for scientific inquiries

Contact

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Islamic Azad University

Full name of responsible person
Zohre Amir khani

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for updating data

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Position
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Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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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

Not applicable

Title and more details about the data/document

Individually nonidentifiable information of participants will be shared in this study. Also, the protocol, results and statistical analysis of the study will be published in the relevant articles.

When the data will become available and for how long

Unidentifiable personal information of the participants will be available after the publication of the related articles.

To whom data/document is available

Unidentifiable personal information of the participants will be made available to other researchers at academic institutions.

Under which criteria data/document could be used

Unidentifiable personal information of participants can only be used for research

From where data/document is obtainable

send an email: hamidipour.sina.nu@mshdiau.ac.ir

What processes are involved for a request to access data/document

Researchers in academic institutions can send their request by e-mail to the mentioned email. The data will be sent to them after consulting and approving the research team.

Comments