

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of eight weeks of aerobic exercise with Propolis supplementation on some inflammatory and immune markers in hemodialysis patients

Protocol summary

Study aim

The effect of eight weeks of aerobic exercise with Propolis supplementation on some inflammatory and immune markers in hemodialysis patients

Design

A double-blind, randomized, parallel clinical trial

Settings and conduct

Hemodialysis department of 22 Bahman Hospital, Neishabur city

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. An age range of 30 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; 2. The acute cardiac event in the last six months; 3. Taking any medicine outside the routine treatment protocol of hemodialysis patients; 4. Any allergy to honey and its compounds; 5. Smoking, drug addiction, or alcohol consumption 6- The impossibility of sports activities 7- Hemodynamic instability of the patient that the attending physician does not allow the patient to participate in study 8- Simultaneous participation in other interventional research

Intervention groups

The group receiving propolis supplement + aerobic exercise with mild to moderate intensity The group receiving placebo + mild to moderate aerobic exercise

Main outcome variables

CRP Serum Albumin level CRP/Alb Investigating the ratio of neutrophils to lymphocytes and platelets Total Antioxidant capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230131057295N1**

Registration date: **2023-02-27, 1401/12/08**

Registration timing: **prospective**

Last update: **2023-02-27, 1401/12/08**

Update count: **0**

Registration date

2023-02-27, 1401/12/08

Registrant information

Name

Iman Rahnama

Name of organization / entity

Binaloud institute of higher education

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of aerobic exercise with Propolis supplementation on some inflammatory and

immune markers in hemodialysis patients

Public title

The effect of aerobic exercise concurrent with propolis supplementation in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

An age range of 30 to 65 years ESRD patients on hemodialysis treatment Perform hemodialysis 3 days a week Willingness to participate in research Absence of any allergy to honey and its derivatives Ability to perform aerobic exercise

Exclusion criteria:

BMI above 30 Acute heart attack in the last six months Any allergy to honey and its compounds Taking any medicine outside the routine treatment protocol of hemodialysis patients Smoking, drug addiction or alcohol consumption Having any acute illness or cancer, autoimmune diseases

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the people with kidney failure undergoing hemodialysis referred to 22 Bahman Neishabur Hospital, 84 patients will be included in this study based on the inclusion criteria and will be classified according to age and gender in a block manner, the participants will be randomly assigned to one of two intervention and control groups will be included.

Blinding (investigator's opinion)

Double blinded

Blinding description

Capsules in all groups have been standardized in terms of appearance, color and smell. As each person enters the study based on the randomly generated sequence, the medication package in which the desired code is recorded will be assigned to the person, and therefore, before choosing the person, no one will be aware of the type of treatment he will receive. Finally, the data and information are given to the statistician with a special code for each group so that the statistician is also blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Neyshabur University of Medical Sciences

Street address

Baghcheban town, Neishabur University of Medical Sciences, Medical Sciences Pardis

City

Neyshabur

Province

Razavi Khorasan

Postal code

14139-93186

Approval date

2023-01-04, 1401/10/14

Ethics committee reference number

IR.NUMS.REC.1401.037

Health conditions studied

1

Description of health condition studied

Patients with complete renal failure undergoing hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

CRP

Timepoint

At the beginning and end of the study

Method of measurement

ELISA

2

Description

Albumin

Timepoint

At the beginning and end of the study

Method of measurement

BROMOCRESOL GREEN

3

Description

CRP to albumin ratio

Timepoint

At the beginning and end of the study

Method of measurement

It will be obtained by dividing the serum levels of C-reactive protein by albumin

4

Description

The ratio of neutrophils to lymphocytes

Timepoint

At the beginning and end of the study

Method of measurement

After measuring neutrophils and lymphocytes with a cell counter, these items will be divided and the ratio will be obtained.

5

Description

The ratio of lymphocytes to platelets

Timepoint

At the beginning and end of the study

Method of measurement

After measuring lymphocytes and platelets with a cell counter, these items will be divided and the ratio will be obtained.

6

Description

Total antioxidant capacity

Timepoint

At the beginning and end of the study

Method of measurement

By colorimetric method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg of propolis extract daily (two 250 mg propolis capsules, one after lunch and one after dinner) and walking 3 days a week with an exercise program according to the protocol for eight weeks. Capsules containing alki extract Propolis is prepared by Asal Shohdina Ya Golha company with registration number P0032.

Category

Treatment - Drugs

2

Description

Control group: The second group will take 500 mg of the same placebo daily (two capsules of 250 mg of placebo, one after lunch and one after dinner) and walk 3 days a week with an exercise program according to the protocol for eight weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Ali Asghar Dalili

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Imam Khomeini street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

Seyyed Mostafa Arabi

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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

Neyshabour University of Medical Sciences

Proportion provided by this source

1

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**

Binaloud institute of higher education

Full name of responsible person

Iman Rahnama

Position

Postgraduate student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Neyshabour University of Medical Sciences

Full name of responsible person

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The anonymous information of the participants in this study will be shared if an official request is submitted to the university and approved by the research council of the relevant university. Also, the results of this study will be published in relevant articles.

When the data will become available and for how long

There is no specific time limit.

To whom data/document is available

Only researchers who formally request through the university research council will be granted access if the council approves.

Under which criteria data/document could be used

In order to pool the results of several studies, data will be shared.

From where data/document is obtainable

Vice President of Research and Technology of Neyshabur
University of Medical Sciences

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

The request should be sent in the form of an official
proposal to the Research and Technology Vice-
Chancellor of Neyshabur University of Medical Sciences
and followed up through the council of this university.

Comments