Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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 plateletsTotal 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

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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
Street address
Imam Khomeini street
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for updating data

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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