Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effectiveness of propolis dietary supplement on metabolic syndrome and its components in patients with metabolic syndrome: a randomized, controlled, double-blinded clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of propolis dietary supplement on metabolic syndrome and its components in patients with metabolic syndrome: a randomized, controlled, double-blinded clinical trial

Design

A randomized, double-blind, clinical trial with a parallel groups design of 60 patients.

Settings and conduct

In this study, we select 60 individuals with metabolic syndrome who refer to clinics affiliated to the university of medical science, Esfahan and we will divide them in to 2 groups receiving propolis supplement and placebo. For proper blindness, the drug and placebo will be exactly the same and non of the participants and researchers will be aware of them until the end of the study. At the beginning of the study and 12 weeks after the intervention, biochemical evaluation, anthropometry and blood pressure measurement will be performed. During this period, all patients receive healthy lifestyle recommendations

Participants/Inclusion and exclusion criteria

inclusion criteria: patients with metabolic syndrome according to NCEP-ATP III, adults 20-60 years old, willingness to participate, ability to read and write; criteria for not entering: pregnancy or lactation, having certain diseases, tobacco and alcohol consumption, adherence to a weight-loss diet or physical activity program, insulin injection, Change in the type and dosage of medication from 3 months before entering the study

Intervention groups

Intervention groups: 2 tablets of 350 mg daily containing 250 mg of propolis extract before lunch and dinner, for 12 weeks. Placebo groups: 2 tablets daily containing 350 mg of microcrystalline cellulose before lunch and dinner

Main outcome variables

Fasting blood sugar; Triglyceride; Total cholesterol; High-density lipoprotein; Low-density lipoprotein; Insulin; HOMA-IR index; Weight; Waist; BMI; Blood pressure; C-reactive protein, Quality of life, Mood status

General information

Reason for update

Change in some exclusion criteria

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N49**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-09, 1401/05/18**
Update count: **1**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of propolis dietary supplement on metabolic syndrome and its components in patients with metabolic syndrome: a randomized, controlled, double-blinded clinical trial

Public title
Evaluation of the effectiveness of propolis dietary supplement on metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with metabolic syndrome according to (NCEP-ATP III) Willingness to participate in the study Adults 20-60 years old Having the ability to read and write

Exclusion criteria:
Pregnancy and lactation Having the following disease: Malignancies or cancer, type I diabetes, nephrotic syndrome, kidney and lung disease, biliary disease, and HIV Sensitivity to bee products Adherence a weight loss diet or physical activity program Tobacco and alcohol consumption Insulin injection Change in the type and dosage of medication from 3 months before entering the study

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will conduct based on the permuted block randomization method. Each block will have a capacity for 4 subjects. Then, within each block, subjects will be randomly assigned to treatment or placebo. Random assignment will be done using a random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
For proper blinding, the drug and placebo will be exactly the same in size, color, odor, and packing, and none of the participants and researchers will be aware of them until the end of the study, except for the pharmacist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib Street

City
Esfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-12-06, 1399/09/16

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.595

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Homeostasis model assessment insulin resistance (HOMA-IR)

Timepoint
At the beginning of the study and 12 weeks after supplementation

Method of measurement
(fasting plasma glucose × fasting Insulin)/22.5

Secondary outcomes

1

Description
Serum insulin

Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Laboratory method

2

Description
Fasting blood sugar
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Colorimetric analysis method and by autoanalyzer

3

Description
Triglyceride
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Colorimetric analysis method and by autoanalyzer

4

Description
Cholesterol
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Colorimetric analysis method and by autoanalyzer

5

Description
High-density lipoprotein (HDL)
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Colorimetric analysis method and by autoanalyzer

6

Description
Low density lipoprotein (LDL)
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Colorimetric analysis method and by autoanalyzer

7

Description
C-reactive protein (CRP)
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Immunoturbidimetric

8

Description
Blood pressure
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Barometer

9

Description
Weight
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Digital scale

10

Description
Waist Circumference
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Non-elastic meter

11

Description
Body mass index (BMI)
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
Weight/ (Height*Height)

12

Description
Quality of Life
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
A validated questionnaire- 36-Item Short Form Health Survey (SF-36)

13

Description
Mood status (Stress, depression, anxiety)
Timepoint
At the beginning of the study and 12 weeks after supplementation
Method of measurement
A validated questionnaire DASS-21

Intervention groups

1

Description
Intervention group: Daily consumption of two 350 mg capsules that each capsule contains 250 mg of propolis extract and 100 mg of safe and ineffective combination of microcrystalline cellulose as a supplemental formulation, made by Reyhan Naghsh Jahan Pharmaceutical Company, Isfahan before lunch and dinner for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Daily consumption of two placebo capsules that each capsule contains 350 mg of microcrystalline cellulose, made by Reyhan Naghsh Jahan Pharmaceutical Company, Isfahan before lunch and dinner for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Research Center
Full name of responsible person
Dr. Mansour Siavash Dastjerdi
Street address
Khoram Street
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8187698191
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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askari@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical 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
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Position
Professor
Latest degree
Ph.D.
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Person responsible for scientific inquiries

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Gholamreza Askari
Position

Ph.D of nutrition, Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Gholamreza Askari

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
Data can be shared after people are not identified.

When the data will become available and for how long
Access 1 year after publishing results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data will be available in order to know the details of the research and any secondary analysis of the data is subject to the permission of the project owner.

From where data/document is obtainable
Hezar Jarib St., Isfahan University of Medical Sciences, Nutrition college, Department of Community Nutrition, Dr. Gholamreza Askari, Askari@mui.ac.ir

What processes are involved for a request to access data/document
The communication will be possible through the electronic mail given in the previous section.

Comments