Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the Effect of Propolis Supplement on Metabolic, Hormonal, Inflammatory, Clinical and Metabolic Indices in Women with Polycystic Ovary Syndrome

Protocol summary

Study aim

Determining the effect of Propolis supplement on metabolic, hormonal, inflammatory, clinical, and basal metabolic rate in women with Polycystic ovary syndrome

Design

Two arms parallel-group randomized trial with control group, double-blind, phase 2 on 70 patients, randomization software (RAS) was used for randomization.

Settings and conduct

70 women with Polycystic ovary syndrome referred to Motazedi Medical Center are diagnosed and selected by gynecologists and endocrinologists if there are at least two factors based on Rotterdam criteria. Individuals will be randomly divided into two groups: placebo and intervention. Researchers and participants were blinded by the study group. For this purpose, the codes assigned to each participant are grouped by a third party (unaware of the study)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female, Aged 18-45 years, Having Polycystic ovary syndrome according to Rotterdam criteria, Body mass index (BMI) greater than or equal to 18.5 kg/m2; Exclusion criteria: Pregnancy, Lactation, Insulin injection, People with autoimmune diseases, People with gastrointestinal diseases, People with liver disease, People with thyroid disease, People with cardiovascular disease, People with a severe respiratory illness such as asthma and chronic bronchitis, Consume any vitamins, minerals, and dietary supplements, Existence of allergies to Propolis, Honey, and bee products

Intervention groups

Patients in the intervention group will take 300 mg of Propolis supplement three times per day, one hour after each meal with a glass of water. Patients in the placebo group will take three placebo tablets daily with the same shape, color, and size similar to the Propolis supplement. The duration of the intervention will be 12 weeks.

Main outcome variables

High-sensitivity C-reactive Protein; Insulin Resistance Index; Free androgen index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200912048693N1**
Registration date: **2020-09-17, 1399/06/27**
Registration timing: **prospective**

Last update: **2020-09-17, 1399/06/27**
Update count: **0**

Registration date

2020-09-17, 1399/06/27

Registrant information

Name

Amir Saber

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2009

Email address

amir.saber@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-20, 1399/08/30

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Propolis Supplement on Metabolic, Hormonal, Inflammatory, Clinical and Metabolic Indices in Women with Polycystic Ovary Syndrome

Public title
Evaluation of the Effect of Propolis Supplement on Women with Polycystic Ovary Syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having Polycystic ovary syndrome according to Rotterdam criteria Body mass index (BMI) greater than or equal to 18.5 kg/m2
Exclusion criteria:
Pregnancy Lactation Insulin injection People with autoimmune diseases People with gastrointestinal diseases People with liver disease People with thyroid disease People with cardiovascular disease People with severe respiratory illness such as asthma and chronic bronchitis Consume any vitamins, minerals and dietary supplements Existence of allergies to Propolis, Honey and bee products
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Due to simple randomization, each person participating in the study is assigned a random code created by random allocation software (RAS) and these codes are divided into two groups by a third person who is unaware of the study and its conditions.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in this study do not know whether they are in the intervention or control group, Researchers do not know which participant is in the intervention or control group. In order to blindness, each participant in the study is assigned a random code created by random allocation software (RAS), and these codes are divided into two groups by a third person who is unaware of the study and its conditions.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Faculty of Nutrition Sciences and Food Industry, next to Farabi hospital, Esar square, Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6719851552
Approval date
2020-09-12, 1399/06/22
Ethics committee reference number
IR.KUMS.REC.1399.564

Health conditions studied

1

Description of health condition studied
Polycystic Ovary Syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
High-sensitivity C-reactive Protein
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzyme-Linked Immunosorbent Assay

2

Description
Insulin Resistance Index
Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

HOMA-IR={[Fasting insulin (microunits/ml)] × [Fasting Glucose (mmol/l)]}/22.5

3

Description

Free androgen index

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Free androgen index = 100 X [(Total Testosterone)/Sex hormone binding globulin]

Secondary outcomes

1

Description

Body mass index

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Body mass index=body mass (kg)/ the square of the body height (m)

2

Description

Omentin-1

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

3

Description

Chemerin

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

4

Description

Neopterin

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

5

Description

Testosterone

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

6

Description

Follicle-stimulating hormone

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

7

Description

Luteinizing hormone

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

8

Description

Dehydroepiandrosterone

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

Intervention groups

1

Description

Intervention group: Consumption material: Propolis; Chemical composition and concentration: Different types of Flavonoids, Cinnamic acid derivatives, 50% plant gum or resin, 30% wax, 10% essential fatty acids, 5% pollen, and 5% organic compounds, vitamins and minerals; Dosage: 300 mg per day; Daily usage: 3 times a day; Duration of use: 12 weeks; How to use: orally; Manufacturer: Shahdineh Golha Company

Category

Rehabilitation

2

Description

Control group: Consumption material: Avicel; Chemical composition: Cellulose microcrystalline; Dosage: 300 mg per day; Daily usage: 3 times a day; Duration of use: 12 weeks; How to use: orally; Manufacturer: Pishgaman Shimi

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Motazedi Educational and Medical Center of Kermanshah University of Medical Sciences

Full name of responsible person
Amir Saber

Street address
Motazedi Clinic, Ferdowsi Square, Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Farid Najafi

Street address
Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd.

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Web page address
https://vc-research.kums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research, Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Amir Saber

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Faculty of Nutrition Sciences and Food Industry, Next to Farabi hospital, Esar Square, Kermanshah

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Amir Saber

Position
Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Amir Saber

Position
Assistant Professor

Latest degree
Ph.D.

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
All data related to the primary and secondary outcome will be shared

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

To whom data/document is available
Researchers in academic and scientific institutions, as well as people in the industry, are allowed to access the data

Under which criteria data/document could be used
Anyone who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All of these steps will not take more than 10 days.

From where data/document is obtainable
Amir Saber, Assistant Professor, Kermanshah University of Medical Sciences, Faculty of Nutrition Sciences and Food Industry, Address: Faculty of Nutrition Sciences and Food Industry, Next to Farabi hospital, Esar Square, Kermanshah Postal code: 6719851552 Phone: 0098 83 37102009 Email: amir.saber@kums.ac.ir

What processes are involved for a request to access data/document
After sending the request by the applicant and confirming the goals and method of the study by all project researchers, the data will be provided by email in less than 10 days.

Comments