

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of propolis dietary supplement consumption on indices of high-sensitivity C-reactive protein, testosterone hormone and metabolic profile in women with polycystic ovary syndrome (PCOS)

#### Protocol summary

##### Study aim

The effect of propolis diet supplement on the status of the body's inflammatory index, testosterone and metabolic profile in women with polycystic ovary syndrome

##### Design

Randomized double-blind, control trial of phase 3 with parallel groups design of 56 patients. An authentic website is used for randomization.

##### Settings and conduct

We select 56 women with PCOS referring to the gynecologist clinic located in Shahid Beheshti Hospital in Isfahan and we will divide them into 2 groups receiving propolis supplement and placebo. For proper blindness, the drug and placebo will be exactly the same and none 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, blood samples will be taken and the necessary measurements will done. During this period, participants are advised to eat a healthy diet and perform 30-45 minutes of physical activity daily.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Diagnosis of PCOS according to the Rotterdam criteria, Age between 18 and 45 years, Do not take any drug other than metformin Criteria for not entering: Hormone therapy or taking contraceptive pills, History of gestational hypertension, Pregnancy or breastfeeding, Tobacco and alcohol consumption, having certain diseases

##### Intervention groups

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

##### Main outcome variables

Fasting blood sugar; Insulin; HOMA-IR index; triglyceride; Cholesterol; High-density lipoprotein; Low-density lipoprotein; testosterone; High sensitivity C-reactive protein; Status of menstrual disorders; blood pressure; Height; Weight; Waist; Waist to hip ratio; BMI

#### General information

##### Reason for update

Due to the coronavirus conditions in the country and the impossibility of starting the project on the predicted dates, it was necessary to change the start and end dates of the recruitment.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121216011763N51**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **prospective**

Last update: **2022-08-17, 1401/05/26**

Update count: **2**

##### Registration date

2021-03-07, 1399/12/17

##### 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**

2021-10-08, 1400/07/16

**Expected recruitment end date**

2022-06-01, 1401/03/11

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of propolis dietary supplement consumption on indices of high-sensitivity C-reactive protein, testosterone hormone and metabolic profile in women with polycystic ovary syndrome (PCOS)

**Public title**

The effect of propolis dietary supplement on the status of hs-CRP inflammatory index, sex hormone testosterone levels and metabolic profile of women with polycystic ovary syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of PCOS according to Rotterdam criterion: According to this criterion, the subjects should have two of the three diagnostic features of PCOS: 1- Oligomenorrhea and anovulation 2- Hyperandrogenism 3- Polycystic ovary Age between 18 and 45 years Not to have sensitivity to bee products Not to take any specific drug more than metformin Not to have laparoscopic ovarian surgery and assisted reproductive technology

**Exclusion criteria:**

Hormone therapy or taking contraceptive pills (OCP) History of gestational hypertension Pregnancy or breastfeeding Menopause Tobacco and alcohol consumption Having following diseases: Diabetes, cardiovascular, hepatic, renal, thyroid, asthma, neoplasm

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be divided into intervention and control groups using block classified randomization. The following authoritative site will be used to allocate the intervention in the above-mentioned manner.

<https://www.sealedenvelope.com/simple-randomiser/v1/lits> In this way, people are randomly divided into two groups of intervention and control using quadruple blocks based on age. It is noteworthy that participants and outcome assessors will not be aware of patient grouping and will be blind to it.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

For proper blinding, the drug and placebo will be exactly the same in color, size, and odor, 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 St., Isfahan University of Medical Sciences, School of Nutrition, Department of Community Nutrition, Dr. Gholamreza Askari

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**Postal code**

8174673461

**Approval date**

2020-11-25, 1399/09/05

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1399.587

**Health conditions studied****1****Description of health condition studied**

Polycystic ovarian syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Polycystic ovarian syndrome

**Primary outcomes****1****Description**

Homeostatic model assessment of insulin resistance (HOMA-IR)

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

formula= (fasting plasma glucose(mmol/l) \*fasting insulin (IU/ml))/22.5

## Secondary outcomes

### 1

**Description**

testosterone

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Blood samples by enzymatic method

### 2

**Description**

triglyceride

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Blood samples by enzymatic method

### 3

**Description**

cholesterol

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Blood samples by enzymatic method

### 4

**Description**

high density lipoprotein

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Blood samples by enzymatic method

### 5

**Description**

low density lipoprotein

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Blood samples by enzymatic method

### 6

**Description**

fasting blood sugar

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Blood samples by enzymatic method

### 7

**Description**

insulin

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

blood samples by ELISA kits

### 8

**Description**

Highly sensitive C-reactive protein

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

blood samples by ELISA kits

### 9

**Description**

blood pressure

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

barometer

### 10

**Description**

weight

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Digital scales

### 11

**Description**

waist

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Inelastic meters

### 12

**Description**

hip

**Timepoint**

Before study and 12 weeks after supplementation

**Method of measurement**

Inelastic meters

## Intervention groups

### 1

**Description**

Intervention group: Daily consumption of two 350 mg tablets containing 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 350 mg placebo tablets containing 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**

Shahid Beheshti hospital

**Full name of responsible person**

Dr. Hatav Ghasemi Tehrani

**Street address**

Shahid Beheshti Isfahan, Obstetrics and Gynecology Hospital, Ostad Motahhari St., Metal Bridge.

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5354181848

**Phone**

+98 31 3234 6338

**Email**

Hatav.tehrani2014@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Askari

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

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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.

**Other areas of specialty/work**

Nutrition

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Gholamreza Askari

**Position**

Ph.D of nutrition, Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elahe Abbasi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Web page address**

**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 allowed due to the permission of the project owner.

**From where data/document is obtainable**

Dr. Gholamreza Askari, Department of Community Nutrition, School of Nutrition, Isfahan University of Medical Sciences, Hezar Jarib St. Askari@mui.ac.ir

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

Submit your application via email to eabbasi97@yahoo.com if your application is approved, you will receive the documents within a maximum of 1 month.

**Comments**