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/lists 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
City
Isfahan
Province
Isfehan
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.

City

Isfahan

Province

Isfehan

Postal code

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 3151

Email

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

Street address

Department of Community Nutrition, Faculty of Nutrition, Isfahan University of Medical Sciences, Hezar Jerib St.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 3171

Email

askari@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Position

Ph.D of nutrition, Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Community Nutrition, Faculty of Nutrition, Isfahan University of Medical Sciences,

Hezar Jerib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3171

Fax

Email
askari@mui.ac.ir

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
Nutrition

Street address
Department of Community Nutrition, Faculty of Nutrition, Isfahan University of Medical Sciences, Hezar Jerib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3171

Fax

Email
eabbasi97@yahoo.com

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