Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of royal jelly supplementation on hormonal status, insulin resistance and inflammatory factors in patients with polycystic ovary syndrome: pilot study

Protocol summary

Study aim

Determination of the effect of royal jelly supplementation on hormonal status,insulin resistance and inflammatory factors in patients with (PCOS)

Design

A parallel-group, triple-blind, randomized, phase 2 clinical trial in 24 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This pilot study will be conducted on 24 women with (PCOS) in Imam Reza Hospital of TBZMED. The patients included in the study will be randomly divided into two groups receiving placebo and intervention receiving 1000 mg of royal jelly per day. The duration of the intervention will be 60 days, and the side effects of the supplement will be recorded by recording all clinical symptoms. Placebo capsules will be prepared and packaged in the form of the supplement. In this study, the researcher, the patient, the laboratory technician and the results analyst will be blinded to the study groups. Before and after the intervention, fasting blood will be taken from all patients and all blood biochemical factors including inflammatory indices, sex hormones, serum insulin and fasting blood sugar will be measured.

Participants/Inclusion and exclusion criteria

Entry criteria: Female volunteers aged 15-45 with clinical symptoms of hyperandrogenism. Exclusion criteria: Lack of consent to participate in the study, Pregnancy, breastfeeding, Suffering from diseases such as Autoimmune, Digestive, Liver, Thyroid and Unstable Cardiovascular diseases, severe respiratory disease, Taking any type of vitamin and mineral supplements in the last six months, people with a history of allergies

Intervention groups

Control group: Receive placebo medicine once a day for two months. Intervention group: They receive 100 mg royal jelly tablets daily for two months.

Main outcome variables

Estrogen, Testosterone, SHBG, FBS, Insulin, Interleukin 6, hs-CRP, BMI

General information

Reason for update

Thanks to the scientific efforts of the officials and colleagues of the center. In this study, the age of the participants was considered to be 18-45 years old. Considering that it is actually necessary to pass 2 years from Menarche to enter the study, there were females who were 15 to 18 years old year and had spent 2 years and so entered the study. Therefore, please change the minimum age from 15 to 18 years.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190212042686N3**
Registration date: **2022-12-28, 1401/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-09, 1402/09/18**
Update count: **1**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name
majid Mobasseri
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-12-05, 1401/09/14
Expected recruitment end date
2023-12-05, 1402/09/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of royal jelly supplementation on hormonal status, insulin resistance and inflammatory factors in patients with polycystic ovary syndrome: pilot study

Public title
The effect of royal jelly supplementation on hormonal status,insulin resistance and inflammatory factors in patients with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female volunteers aged 15-45 with clinical symptoms of hyperandrogenism
Exclusion criteria:
Pregnancy Breastfeeding Having diseases such as autoimmune diseases Digestive diseases Liver disease Thyroid Unstable cardiovascular diseases Severe respiratory disease (Asthma and Chronic bronchitis) Taking any type of vitamin and mineral supplements in the last six months People with a history of allergies
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified permuted block randomization will be applied to stratify participants into different stratum and blocks based on probable confounders including age and BMI. Each block will be randomly allocated to the intervention or control groups. The sequence of the blocks will be prepared for each stratum Random Allocation Software (RAS). For each patient in a definite block, a matched person in terms of the aforementioned variables would be considered in that block. Participants and investigators will be blind to the trial group assignments until the end of the study and data analysis.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo capsules will be prepared and packaged as well as the supplement form. Coding of packages containing supplements and placebos will be done by someone other than the researchers as A, B, and volunteers will be randomly assigned to placebo and intervention groups. In this study, the researcher, the patient, the laboratory technician and the results analyst will be blind to the study groups (triple blind).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Tabriz University of Medical Sciences
Street address
Ethics Committee,Tabriz University of Medical Sciences, Golgasht Street , Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Approval date
2022-12-04, 1401/09/13
Ethics committee reference number
IR.TBZMED.REC.1401.808

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
Estrogen
Timepoint

Baseline and 2 months after the treatment

Method of measurement

ELISA Test

2

Description

Testosterone

Timepoint

Baseline and 2 months after the treatment

Method of measurement

ELISA Test

3

Description

Sex Hormone-Binding Globulin (SHBG)

Timepoint

Baseline and 2 months after the treatment

Method of measurement

ELISA Test

4

Description

Fasting blood sugar

Timepoint

Baseline and 2 months after the treatment

Method of measurement

Electrochemiluminescence Test

5

Description

Insulin resistance with HOMA-IR score

Timepoint

Baseline and 2 months after the treatment

Method of measurement

Electrochemiluminescence Test

6

Description

Interleukin 6

Timepoint

Baseline and 2 months after the treatment

Method of measurement

Electrochemiluminescence Test

7

Description

hs-CRP

Timepoint

Baseline and 2 months after the treatment

Method of measurement

Electrochemiluminescence Test

8

Description

Body mass scale

Timepoint

Baseline and 2 months after the treatment

Method of measurement

Weight scale and stadiometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will receive Royal jelly capsule (1000 mg) once a day manufactured by STP pharma factory for 2 months.

Category

Treatment - Drugs

2

Description

Control group: The placebo capsule filled with starch is completely similar to the used supplement and is taken once a day for two months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam Reza Hospital

Full name of responsible person

Dr.Majid Mobasseri

Street address

Department of Endocrinology, Imam Reza Hospital, Daneshgah Square, Tabriz, East Azarbaijan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

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Vice chancellor for Research,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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Grant name

Grant code / Reference number
70751

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
dr.Majid Mobasseri
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinology and Metabolism
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Department of Endocrinology, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

Access starting 6 months after publication

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.

From where data/document is obtainable

The researchers (student and her supervisor)

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

After the publication of the article, the researchers should have access to the study documents through an email request from the person in charge of the project (mobasserim@tbzmed.ac.ir).

Comments