Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

The effect of curcumin supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of curcumin supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Design

Study design: Randomized double-blind placebo-controlled trial, All participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two groups. Randomization will be done by the use of computer software.

Settings and conduct

Among patients with polycystic ovary syndrome referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years. Exclusion criteria: Individuals with neoplastic disorders, cardiovascular diseases, malabsorptive disorders, and current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications

Intervention groups

Intervention group: 500 mg curcumin, once a day, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and gene expression related to insulin and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

The revisions were accordance with the original approved proposal.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N50**
Registration date: **2019-03-20, 1397/12/29**
Registration timing: **retrospective**

Last update: **2020-01-30, 1398/11/10**
Update count: **1**

Registration date

2019-03-20, 1397/12/29

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-23, 1397/11/03

Expected recruitment end date

2019-02-09, 1397/11/20

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

Scientific title
The effect of curcumin supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Public title
The effect of curcumin supplementation in treatment of women with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with polycystic ovary syndrome Individuals aged 18 to 40 years
Exclusion criteria:
Individuals with neoplastic disorders cardiovascular diseases malabsorptive disorders current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Kosar clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
1771844351
Approval date
2019-01-22, 1397/11/02
Ethics committee reference number
IR.ARAKMU.REC.1397.299

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
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

2

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Expressed levels of GLUT-1 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of PPAR-γ gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of LDL-R gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: 500 mg curcumin , once a day, for 12 weeks orally
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Clinic
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
City
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1771844351
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+98 31 5546 3378
Email
jamilian_m@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Arjomandzadegan
Street address
Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Ghotbe Ravandi Boulevard, Kashan
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Person responsible for updating data

Contact
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Other areas of specialty/work
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1771844351
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asemi_z@kaums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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