Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The effect of curcumin supplementation on glycemic control, antioxidant and anthropomethric indices, PGC1-α and SIRT1 gene expression in polycystic ovary syndrome(PCOS) women

Protocol summary

Study aim

The effect of curcumin supplementation on glycemic control, antioxidant and anthropomethric indices, PGC1-α and SIRT1 gene expression in polycystic ovary syndrome(PCOS) woman

Design

At the beginning of the study, the demographic information of participants (age, sex, education and diet weight loss) were completed by the researcher face to face. To assess the diet information, 3 of the 24-hour questionnaires were used (2 usual days and 1 day off) at the beginning and the end of the study. To evaluate the individual's physical activity, the International Short-Term Physical Activity Questionnaire (IPAQ) is used at the beginning and end of the study. Anthropometric measurements are performed at the beginning and end of the study. Ten cc blood samples will taken for biochemical factors assessment after 12-14 hours of fasting, at the beginning and the end of 90 days.

Settings and conduct

Patients with polycystic ovary syndrome referring to Arash Hospital, Tehran University of Medical Sciences are recruited in this study. participants randomly assigned to intervention and placebo group. participants, data gathering staff and statistical counselor will be blind of participants allocation

Participants/Inclusion and exclusion criteria

Women with polycystic ovaries based on Rotterdam diagnostic criteria and other endocrine disorders such as high prolactin levels, increased ovarian outer layer thickness, congenital adrenal hyperplasia, Cushing's syndrome, and orogenic or acromegaly producing tumors are considered for inclusion in this study.

Intervention groups

The intervention group received three capsules of 500 mg curcumin daily and control group receive three placebo capsules (maltodextrin) for 3 months.

Main outcome variables

PGC1-α gene expression; Sirt1 gene expression; GPx Serum levels; Serum concentration of SOD; Serum concentration of LH; Serum FSH concentration; Serum DHEA levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N50**
Registration date: **2019-01-23, 1397/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-23, 1397/11/03**
Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

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Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin supplementation on glycemic control, antioxidant and anthropomethric indices, PGC1-α and SIRT1 gene expression in polycystic ovary syndrome(PCOS) women

Public title

Curcumin in PCOS

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

The willingness to voluntarily participate in the study Diagnosis of polycystic ovary syndrome by a specialist physician in the mild to moderate phase Having impaired glucose tolerance (IGT) The consumer is just one of the metformin or clomiphene drug groups Age more than 18 years old BMI higher than 25 and less than 30 kg/m2

Exclusion criteria:

Change the type and dosage of the drug over the past month Congenital hormonal disorders, autoimmune diseases, cancer, inflammatory diseases, hyperthyroidism and hypothyroidism, infections, pregnancy or lactation in women, or use of contraceptive pills The use of multi-vitamin-mineral, omega-3, polyphenolic and antioxidant supplements, as well as the use of anticoagulants such as heparin and warfarin or aspirin, blood cholesterol-lowering drugs (statins), NSAIDs, such as ipobrofen, aspirin and diclofenac, Antihistamines, calcium channel antagonists such as nifedipine, anti-TNF drugs (infliximab, adalimumab and cinnura), glucocorticosteroids (cortisone, prednisolone) and spironolactone during in the past month.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 72 subjects in two groups of 36 participants in each group. Block randomization method was designed using statistical software Stata Version 13. The number of blocks considered is 6.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The random allocation list will be provided only to the statistical consultant. To hide the random allocation process, there are 72 paper labels with randomized 10-digit random codes and a specific frame that identifies the relevant treatment and will be the only methodologist of the design of the code. Labels will be arranged in random order on the drug packs. The drug packs will be arranged in a randomized random list. When the physician announces the eligibility of a patient, the methodologist will provide the package patient with the package. The person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and who is unaware of all the processes performed will be used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

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Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.690

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
Fasting Blood Sugar
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

2

Description
Fasting Insulin
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

3

Description
PGC1-α gene expression
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
Real Time RT-PCR

4

Description
Sirt1 gene expression
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
Real Time RT-PCR

Secondary outcomes

1

Description
Serum GPx
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

2

Description
Serum SOD
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

3

Description
Serum Concentration of DHEA hormone
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

4

Description
Serum concentration of LH
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

5

Description
serum Concentration of FSH hormone
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
laboratory kit

6

Description
Insulin resistance
Timepoint
At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)
Method of measurement
Computing

Intervention groups

1

Description
Intervention group: Curcumin (Turmeric Extract) in 500 mg capsules (manufactured by Karen Company, Iran) three times a day for three months
Category
Treatment - Drugs

2

Description
Control group: Placebo (Maltodextrin) with the same shape and design and color of the main intervention in 500 mg capsules
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash hospital
Full name of responsible person
Javad Heshmati
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West 162 alley, Baghdarnia Street, East Farjam Street, Bagheri Highway, Tehran, Iran
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Sponsors / Funding sources

1

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Full name of responsible person
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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
Iran 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
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Farzad Shidfar
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

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
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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
The primary outcome is the capable to share at the end of the study

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Researchers working in academic institutes

Under which criteria data/document could be used
By requesting the correspond, there will be the possibility of using the data

From where data/document is obtainable
Professor Farzad Shidfar School of Public Health Iran University of Medical Science Hemmat, and Chamran Highways crossroad Tehran Iran. Tel: +98 21 86704743 Cell: +98 9123082922 Fax: +98 21 88622707 Email: shidfar.f@iums.ac.ir Additional email: farzadShidfar@yahoo.com

What processes are involved for a request to access data/document
When, an email sent to the correspond author, the data will usually be sent within 5 to 10 business days

Comments