Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the Effect of Curcumin supplementation on Mood Disorders, Lipid, Glycemic and Oxidative Stress Indexes, High-Sensitivity C-reactive Protein, in Women with Polycystic Ovary Syndrome(PCOS).

Protocol summary

Study aim

Effect of Curcumin Supplement on Mood, Lipid, Glycemic and Oxidative Stress, hs-CRP, in PCOS

Design

In this double-blind, randomized, parallel clinical trial study, 60 patients with PCOS referring to Fertility and Infertility Centers in Isfahan who have criteria for entering the study are described by the available sampling method. The subject, goals and method of studying the study are described. Those people who have been diagnosed with a PCOS diagnosis by a doctor and whose disease has become stable and who does not have severe fluctuations in blood parameters, so that they receive a certain dose of medication for their illness , If they wish to participate in this study, they will receive written consent

Settings and conduct

In this interventional study, 60 patients with PCOS referring to Fertility and Infertility Centers in Isfahan who have criteria for entering the study are described by the available sampling method. The subject, goals and method of studying the study are described.

Participants/Inclusion and exclusion criteria

Inclination to participate in the study, the diagnosis of PCOS by a specialist (based on Rotterdam criteria); a group of 18 to 40 years of age; a BMI greater than 25 and less than 35; a fixed type and dosage of medications within 6 Last month; acute and chronic diseases; antioxidant supplements; or any treatment affecting inflammatory factors and oxidative stress biomarkers during the past 6 months

Intervention groups

Patients are randomly blocked divided into the group receiving the supplement of curcumin and placebo. Patients in the group receiving the supplement of curcumin from karen company (n = 30) for 6 weeks daily 1 g (500 mg twice daily) as Capsules, while patients in the placebo group (n = 30) will receive similar capsules with starch during the study

Main outcome variables

Glycemic Indexes, lipids and Oxidative Stress; hs-CRP; Mood

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039511N1**
Registration date: **2018-06-21, 1397/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-21, 1397/03/31**
Update count: **0**

Registration date

2018-06-21, 1397/03/31

Registrant information

Name

Sara Sohaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-22, 1397/05/31

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

Scientific title
Evaluation of the Effect of Curcumin supplementation on Mood Disorders, Lipid, Glycemic and Oxidative Stress Indexes, High-Sensitivity C-reactive Protein, in Women with Polycystic Ovary Syndrome(PCOS).

Public title
The effect of Curcumin on Polycystic Ovary Syndrome.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
PCOS diagnosis by a Specialist (Base on Rotterdam benchmark) Women aged 18 to 40 Years Old (It is preferable not to be at the Age of Development or Menopause). Body mass index larger equal to 25, smaller and equal to 35. stability in the type and dose of medication in the last 6 months. Lack of acute heart disease, Increased Prolactin levels, Liver, Kidney, Digestive, Thyroid and Diabetes, Androgens secreting Tumors. Use of antioxidant supplements and drugs that affect inflammatory and oxidative stress factors. Drug in the last 6 months
Exclusion criteria:
Unwilling to participate in the study Pregnancy Misdiagnosis of demographic or anthropometric information
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Use the randomized block model (random number table) and place each referral in the intervention or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patients and the physician and the people who will perform the tests will not be aware of the fact that the person is using Curcumin supplement or placebo, and only the investigator and data analyst will know how to blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Faculty of Nutrition and Food Sciences., Hezar-Jerib St., Azad Square.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2018-02-09, 1396/11/20
Ethics committee reference number
092 .2 .1396.IR. MUI. REC

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
Malondialdehyde.
Timepoint
The beginning and the end of the study.
Method of measurement
Biochemistry.

2

Description
Total Antioxidant Capacity.
Timepoint
The beginning and the end of the study.
Method of measurement
Biochemistry.

Secondary outcomes

1

Description
Mean changes in the level of the C reactive protein.
Timepoint
The beginning and the end of the study.
Method of measurement
Biochemistry.

2

Description
Depression anxiety stress score.
Timepoint
The beginning and the end of the study.
Method of measurement
Stress Anxiety Depression Questionnaire 7 question.

Intervention groups

1

Description
Intervention group: For 30 patients with Polycystic Ovarian Syndrome, selected by a specialist based on the Rotterdam index, a written consent is given after explaining the topic of the study. In this double-blind clinical trial, 500 mg Curcumin supplement, Karen Yazd, a pure extract of 95% turmeric, are recommended to take two capsules daily (1 g / day) with food.The duration of the intervention is 6 weeks and patients are taken from the patients at the beginning and the end of the intervention by fasting blood samples.Meanwhile, people respond to fill in short international physical activity questionnaires and depression, anxiety and stress personally, as well as the form of food intake, and after explaining how to write their diet, we ask them to bring them in next time.
Category
Treatment - Drugs

2

Description
Control group: Control group: For 30 patients with Polycystic Ovarian Syndrome, selected by a specialist based on the Rotterdam index, a written consent is given after explaining the topic of the study. In this double-blind clinical trial, Placebo (starch) in the same shape and packaging, Iran, Karen Yazd, recommends daily consumption of two capsules (1 g / day) with food.The duration of the intervention is 6 weeks and patients are taken from the patients at the beginning and the end of the intervention by fasting blood samples.Meanwhile, people respond to fill in short international physical activity questionnaires and depression, anxiety and stress personally, as well as the form of food intake, and after explaining how to write their diet, we ask them to bring them in next time
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical and Educational Center Of Shahid Beheshti
Full name of responsible person
Dr.Hatav Ghasemi Tehrani
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Email
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr,Reza Amani
Street address
Faculty of Nutrition and Food Industry., Isfahan University of Medical Sciences., Hezar-herib St., Azadi Square
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rezaamani@hotmail.com
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
Sara Sohaei
Position
Master/Student
Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about Depression Anxiety Stress Scale Questionnaire.
When the data will become available and for how long
6 months after printing results
To whom data/document is available
Researchers of Scientific references.
Under which criteria data/document could be used
Data will only be used in the area of their subject matter.
From where data/document is obtainable
s.sohaei@nutr.ac.ir 09058798237 983136681378+ Sara Sohaei Isfahan, Azadi Square, School of Nutrition
What processes are involved for a request to access data/document
They will send the message to the email after 10 days.
Comments