

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)

Phone

+98 31 3773 5516

Email address

s.sohaei@nutr.mui.ac.ir

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

Isfahan

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

Street address

Motahari St.,Felezi Bridge

City

Isfahan

Province

Isfahan

Postal code

8158858151

Phone

+98 31 3236 7001

Fax

Email

sarasohaei@yahoo.com

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

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3175

Email

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

Bachelor

Other areas of specialty/work

Nutrition

Street address

Azadi Square, School of Nutrition

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3773 5516

Email

s.sohaei@nutr.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Sara Sohaei

Position

Master/ Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Azadi Square, School of Nutrition

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3773 5516

Email

s.sohaei@nutr.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Sara Sohaei

Position

Master/Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Bahar 1., Nazhvan St.

City

Isfahan

Province

Isfahan

Postal code

81856-65843

Phone

+98 31 3773 5516

Email

s.sohaei@nutr.mui.ac.ir

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