

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of cinnamon supplementation on antioxidant status in patients with polycystic ovary syndrome

Protocol summary

Study aim

Objective of study: To Determine the effect of cinnamon on Antioxidant status in patients with polycystic ovarian syndrome.

Design

Randomized, double-blind, placebo-controlled. Population studied: Individuals with polycystic ovarian syndrome were randomly divided into 2 groups for 8 weeks, group 1 receiving cinnamon (3 capsule 500 mg), group 2 placebo group (3 capsule 500 mg placebo), Sample size: 84 people (2 groups of 42). Study Intervention: cinnamon Supplement

Settings and conduct

The aim of this study was to evaluate the effect of cinnamon supplementation on antioxidant status in patients with PCOS. For each person, the general characteristics questionnaire, anthropometric evaluations, Food registration and the International Assessment of Physical Activity (IPAQ) will be completed. To measure all biochemical parameters, 10 cc of venous blood is collected fast (at the beginning and end of the study).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female: 20-38 years old, $25 \leq \text{BMI} < 40$; At least two standard measurement of amenorrhea or oligomenorrhea; Clinical or laboratory hyperandrogenism and Polycystic Ovary on ultrasonography. Exclusion criteria: Thyroid disorders; Hyperprolactinemia, Cushing's syndrome; Liver and kidney diseases; Cardiovascular disease; High blood pressure and diabetes; Pregnant and lactation women; Consumers of anti-obesity and blood lipid-lowering drugs; Anticoagulants and glucocorticoids drugs; Loss weight diet; Smokers; Very active and athletes; Allergic to cinnamon; Seizure and epilepsy disorders; Cerebrovascular disorders; Individuals undergoing infertility treatments and beta-blockers.

Intervention groups

group 1 receiving cinnamon (3 capsule 500 mg) group 2 placebo group (3 capsule 500 mg placebo)

Main outcome variables

Effect of cinnamon supplementation on antioxidant status in patients with polycystic ovary syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100408003664N22**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

rafrafm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cinnamon supplementation on antioxidant status in patients with polycystic ovary syndrome

Public title

Effect of cinnamon supplementation on antioxidant status in patients with polycystic ovary syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Female:20-38 years old, $25 \leq \text{BMI} < 40$; At least two standard measurement of amenorrhea or oligomenorrhea; Clinical or laboratory hyperandrogenism and polycystic ovary on ultrasonography .

Exclusion criteria:

Exclusion criteria: Thyroid disorders; Hyperprolactinemia, Cushing's syndrome; Liver and kidney diseases; Cardiovascular disease; High blood pressure and diabetes; Pregnant and lactation women; Consumers of anti-obesity and blood lipid-lowering drugs; Anticoagulants and glucocorticoids drugs; Loss weight diet; smokers; Very active and athletes; Allergic to cinnamon; Seizure and epilepsy disorders ; Cerebrovascular disorders; Individuals undergoing infertility treatments and beta-blockers.

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables.

Blinding (investigator's opinion)

Double blinded

Blinding description

A placebo and supplement will be packed in the same number in similar envelopes. The method of blindness will be that the supplements and placebo will be delivered to the participants by someone other than the researcher, and the researcher will remain unaware until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Science

Street address

Tabriz University of Medical Science, Nutrition Faculty, Attar Neyshabori, Goldasht street, Tabriz, Iran

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tabriz

Province

East Azarbaijan

Postal code

5138663134

Approval date

2018-09-10, 1397/06/19

Ethics committee reference number

IR.TBZMED.REC.1397.493

Health conditions studied**1****Description of health condition studied**

Polycystic Ovarian Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Malondialdehyde (MDA)

Timepoint

Beginning and end of the intervention

Method of measurement

Serum kit

2**Description**

total antioxidant capacity(TAC)

Timepoint

Beginning and end of the intervention

Method of measurement

Serum kit

Secondary outcomes

1

Description

Physical activity

Timepoint

Beginning and end of intervention

Method of measurement

questioner

2

Description

Diet

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

3-day food record

Intervention groups

1

Description

Intervention group: 3 capsules of 500 mg cinnamon daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Plasebo: 3 capsule 500 mg daily, 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alghadir hospital

Full name of responsible person

Azam Borzoie

Street address

Alghadir hospital, Hengam street, Resalat Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

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

Azam Borzoie

Position

کارشناس ارشد علوم بهداشتی در تغذیه

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

Master of Health Sciences in Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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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