

# 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

**City**

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

##### City

tehran

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 2292

##### Email

s\_borzoie@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Maryam Rafraf

##### Street address

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

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##### Phone

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##### Email

rafrafm@tbzmed.ac.ir

#### 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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s\_borzoie@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Azam Borzoie

**Position**

Master of Health Sciences in Nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

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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