

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Sep 2026

Effects of zinc supplementation on nitric oxide and biomarkers of oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of zinc supplementation on nitric oxide and biomarkers of oxidative stress in women with polycystic ovary syndrome (PCOS).

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 48 women with PCOS eligible and referred to Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Hyperprolactinemia, thyroid disorders, liver or kidney diseases, pregnancy and lactation, the use of medications such as insulin sensitizers, insulin, and diuretics, subjects following a special diet or consuming drugs with an effect on hormonal profile like oral contraceptives (OCP), steroid hormones, or any other drugs probably to affect ovarian action in the last 3 months, T2DM

Intervention groups

Intervention: Patients will be assigned to receive either 50 mg zinc supplement (intervention group: n=24) or placebo (control group: n=24). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure nitric oxide and biomarkers of oxidative stress. Start and End Date of Intervention: 8 weeks

Main outcome variables

Outcomes: Free testosterone, dehydroepiandrosterone (DHEA), alopecia and hirsutism (primary outcome), and other hormonal profiles, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201407115623N24**

Registration date: **2014-11-09, 1393/08/18**

Registration timing: **retrospective**

Last update: **2019-11-01, 1398/08/10**

Update count: **1**

Registration date

2014-11-09, 1393/08/18

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-06-04, 1393/03/14

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of zinc supplementation on nitric oxide and biomarkers of oxidative stress in women with polycystic ovary syndrome

Public title
Effect of supplementation in treatment of polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women aged 18-40 years Patients with PCOS according to Rotterdam criteria
Exclusion criteria:
 Hyperprolactinemia Thyroid disorders Liver or kidney diseases Pregnancy and lactation The use of medications such as insulin sensitizers, insulin, and diuretics. Subjects following a special diet or consuming drugs with an effect on hormonal profile like oral contraceptives (OCP), steroid hormones, or any other drugs probably to affect ovarian action in the last 3 months T2DM

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take zinc supplementation (n=24) or placebo (n=24). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3814113634

Approval date

2014-05-21, 1393/02/31

Ethics committee reference number

4-164-93

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description

Free testosterone

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

2

Description

Dehydroepiandrosterone (DHEA)

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

3

Description

Hirsutism

Timepoint

Baseline and End-of-trial

Method of measurement

Clinical observation

4**Description**

Alopecia

Timepoint

Baseline and End-of-trial

Method of measurement

Clinical observation

Secondary outcomes**1****Description**

17-OH progesterone

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

2**Description**

Prolactin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

3**Description**

FSH

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

4**Description**

LH

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

5**Description**

Hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

6**Description**

Total antioxidant

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

7**Description**

Glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

8**Description**

Nitric oxide

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

9**Description**

Malondialdehyde

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

Intervention groups**1****Description**

Intervention group: Zinc tablet, 50 mg, daily, for 8 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo tablet, daily, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kosar outpatient Clinic

Full name of responsible person

Mehri Jamilian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Arak 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutrition PhD
Latest degree
Ph.D.
Other areas of specialty/work

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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