

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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)

##### Phone

+98 36 1534 3570

##### Email address

asemi\_z@kaums.ac.ir

##### 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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Emam Khomeyni Avenue, Arak

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mehri Jamilian  
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Vice-chancellor for Education and Research, Sardasht  
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**Email**  
mjamilian@arakmu.ac.ir  
**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**

Nutrition  
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## Person responsible for scientific inquiries

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**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

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Associate professor  
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Ph.D.  
**Other areas of specialty/work**  
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**Web page address****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