

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effects of zinc supplementation on insulin resistance and lipid factors in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of zinc supplementation on insulin resistance and lipid profiles 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: 52 women with PCOS eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, 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: Menopause, consume zinc supplements in the last 3 months, smokers, pregnancy, history of diseases including diabetes, liver, kidney and CVD, thyroid disorders, hyperprolactinemia and Cushing's syndrome.

Intervention groups

Intervention: Patients will be assigned to receive either 50 mg zinc supplement (intervention group: n=26) or placebo (control group: n=26).

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles (secondary outcome) will be quantified at 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: **IRCT201406075623N19**
Registration date: **2014-07-16, 1393/04/25**
Registration timing: **retrospective**

Last update: **2019-10-25, 1398/08/03**

Update count: **1**

Registration date

2014-07-16, 1393/04/25

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-07-07, 1393/04/16

Expected recruitment end date

2014-07-16, 1393/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of zinc supplementation on insulin resistance and

lipid factors in women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with PCOS according to Rotterdam criteria
Women aged 18-40 years

Exclusion criteria:

Menopause Consume zinc supplements in the last 3 months Smokers Pregnancy History of diseases including diabetes, liver, kidney and CVD. Thyroid disorders Hyperprolactinemia Cushing's syndrome

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: **52**

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=26) or placebo (n=26). 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

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

1682/1/5/29/پ

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

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

2

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

3

Description

Insulin sensitivity

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

2

Description

Triglycerides

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

3

Description

HDL-cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

4

Description

Total cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

5

Description

LDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

6

Description

VLDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

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

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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81151-87159

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research@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

Nutrition PhD

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Other areas of specialty/work

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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