

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Email address

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	Kashan
Public title	Province
Effect of supplementation in treatment of polycystic ovary syndrome	Isfahan
Purpose	Postal code
Treatment	1771844351
Inclusion/Exclusion criteria	Approval date
Inclusion criteria:	2014-07-06, 1393/04/15
Patients with PCOS according to Rotterdam criteria	Ethics committee reference number
Women aged 18-40 years	1682/1/5/29/پ
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	Health conditions studied
Age	<u>1</u>
From 18 years old to 40 years old	Description of health condition studied
Gender	Polycystic ovary syndrome
Female	ICD-10 code
	E28.2
Phase	ICD-10 code description
3	Sclerocystic ovary syndrome Stein-Leventhal syndrome
Groups that have been masked	Primary outcomes
- Participant - Investigator - Outcome assessor	<u>1</u>
Sample size	Description
Target sample size: 52	Insulin resistance
Randomization (investigator's opinion)	Timepoint
Randomized	Baseline and End-of-trial
Randomization description	Method of measurement
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.	Elisa
Blinding (investigator's opinion)	<u>2</u>
Double blinded	Description
Blinding description	Insulin
Participants, investigators or the assessors of the outcomes are unaware of the study groups.	Timepoint
Placebo	Baseline and End-of-trial
Used	Method of measurement
Assignment	Elisa
Parallel	<u>3</u>
Other design features	Description
	Insulin sensitivity
Secondary Ids	Timepoint
empty	Baseline and End-of-trial
	Method of measurement
	Elisa
Ethics committees	Secondary outcomes
<u>1</u>	<u>1</u>
Ethics committee	Description
Name of ethics committee	Fasting blood sugar
Kashan University of Medical Sciences	Timepoint
Street address	Baseline and End-of-trial
Bolvare Ghotbe Ravandi, Kashan	Method of measurement
City	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

Street address

Shahid Rajaee Avenue, Kashan

City

Kashan

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Isfahan

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1771844351

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asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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Street address

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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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Nutrition PhD

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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