

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of zinc supplementation on metabolic factors in patients with polycystic ovarian syndrome

Protocol summary

Summary

The objective of this randomized double-blind placebo controlled trial is to investigate the effect of zinc sulfate complement on the metabolic and cardiovascular outcomes in Polycystic ovarian syndrome (PCOS). Subjects with PCOS will be recruited from the infertility department of Alzahra hospital in Tabriz. Patients will be randomly assigned to receive either 220mg Zinc Sulfate oral capsule (50 mg/day elemental zinc) or cornstarch placebo capsules for 60 days. Anthropometric measurements (weight, height, waist and hip circumference, waist to hip ratio), blood pressure and biochemical parameters (lipid profile (total cholesterol, LDL and HDL cholesterol and triglyceride concentrations), fasting glucose and insulin level, IL-6 and hs-CRP levels, concentrations of serum zinc and androgens (DHEAS and testosterone), dietary data obtained from 3-day food records and food frequency questionnaire will be measured before and after treatment and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803212017N2**

Registration date: **2009-10-02, 1388/07/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-10-02, 1388/07/10

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2009-08-06, 1388/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation on metabolic factors in patients with polycystic ovarian syndrome

Public title

Zinc supplementation in patients with polycystic ovarian syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women with PCOS diagnosed by the Rotterdam consensus criteria (Presence of 2 of the following 3 conditions: i. Oligo/anovulation ii. clinical or biochemical evidence of hyperandrogenism iii. Polycystic ovaries on ultrasound examination), age 20-45 years, BMI $\geq$ 25, moderate activity Exclusion criteria: Any disease that influence metabolic parameters in this trial

(liver, cardiovascular, kidney or gastrointestinal diseases, hypo/hyper thyroidism, hyperprolactinemia, congenital adrenal hyperplasia, Cushing's syndrome, androgen secreting tumors), insulin consumption, receiving antihypertension drugs, pregnancy, breast feeding, receiving any vitamin or mineral supplements, any special diet.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University Of Medical Sciences

Street address

Tabriz University Of Medical Sciences, Attare
Neishaboori Avenue, Golgasht Street, Tabriz-

City

Tabriz

Postal code**Approval date**

2009-06-01, 1388/03/11

Ethics committee reference number

5/4/2484

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes**1****Description**

zinc serum value

Timepoint

Baseline and at the end of intervention

Method of measurement

atomic absorption spectrophotometry

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

Fasting serum insulin values

Timepoint

Baseline and at the end of intervention

Method of measurement

commercial kits special to assess insulin values .ELISA

2**Description**

Insulin resistance index

Timepoint

Baseline and at the end of intervention

Method of measurement

with HOMA formula

3**Description**

Serum inflammatory values (IL-6, hs-CRP)

Timepoint

Baseline and at the end of intervention

Method of measurement

hs-CRP assess with immunoturbidimetric method
and IL-6 with elayza method

4**Description**

Fasting serum glucose values

Timepoint

Baseline and at the end of intervention

Method of measurement

Enzymatic method, automatic analyzer

5**Description**

Fasting serum lipid profile (LDL,HDL,total cholesterol,TG)

Timepoint

Baseline and at the end of intervention

Method of measurement

Enzymatic method, with special kits for assessing TG,
HDL, total cholesterol and Friedewald equation for
assessing LDL cholesterol

6

Description

systolic and diastolic Blood pressure

Timepoint

Baseline and at the end of intervention

Method of measurement

mercury sphygmomanometer

7

Description

Antropometric indicators (weight-height-BMI-Waist circumference-hip circumference-WHR)

Timepoint

Baseline and at the end of intervention

Method of measurement

Waist and hip circumference measure with a plastic tape meter. Body weight without shoes with calibrated scale accurate to 0.1 kg. Standing height without shoes or socks measure to the nearest 0.1 cm with a stadiometer mounted on a wall. BMI calculated with this equation: $W(kg) / H(m)^2$. WHR calculated with waist circumference/hip circumference.

Intervention groups

1

Description

Zinc Sulfate one capsule a day for 8 weeks, (220 mg zinc sulphate capsule (50 mg elemental zinc)

Category

Treatment - Drugs

2

Description

Placebo one capsule a day for 8 weeks (insoluble corn starch)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital. Tabriz

Full name of responsible person

Fatemeh Pourteymour farde tabrizi

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

1) Vice-chancellor for research of Tabriz University of Medical Sciences 2) Tabriz Nutrition Research

Full name of responsible person

Ali Reza Ostadrahimi

Street address

1) Tabriz University Of Medical Sciences, Tabriz, East Azarbaijan, Iran. 2) Nutrition research center, Golgasht street, Attare Neishabouri Avenue, Health and Nutrition School, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

1) Vice-chancellor for research of Tabriz University of Medical Sciences 2) Tabriz Nutrition Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Pourteymour farde tabriz

Position

MS student in Nutrition

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Pourteymour farde tabrizi

Position

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Other areas of specialty/work**Street address**