Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 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 Polycysitic ovarian syndrome (PCOS). Subjects with PSCO 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

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

ostadrahimi@tbzmed.ac.ir

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 ≥ 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 immunotorbidometric method andIL-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 srum 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 cholestrol and Friedewald equation for assessing LDL cholestrol

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 measureto 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 tbarizi
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 Researc
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 Researc
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
Street address
Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 1334 0540
Fax
Email
fateme.pourteymour@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Pourteymour farde tabrizi

Position
MS student on Nutrition
Other areas of specialty/work
Street address
Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 1334 0540
Fax
Email
fateme.pourteymour@gmail.com
Web page address

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
MS student on Nutrition
Other areas of specialty/work
Street address
Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street, Tabriz
City
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Postal code
Phone
+98 41 1334 0540
Fax
Email
fateme.pourteymour@gmail.com
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