Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of zinc sulfate and folic acid on endocrine indices, CRP and lipid profile in women with polycystic ovary syndrome in 2017-18.

Protocol summary

Study aim

The effect of zinc sulfate and folic acid on endocrine indices, CRP and lipid profile in women with polycystic ovary syndrome

Design

Clinical trial with control group, double-blind, randomized, on 44 patients. The table of random numbers was used for randomization.

Settings and conduct

44 women who aged 18-40 years old with polycystic ovarian syndrome were included in the study according to Rotterdam criteria. Prior to intervention, laboratory factors such as fasting blood sugar (FBS), Dehydroepiandrosterone sulfate (DHEAS), Testosterone, Cholesterol, Triglycerides, High density lipoprotein (HDL) and Low-density lipoprotein (LDL) was measured in subjects. Patients were randomly divided into 4 groups using the random number table and the first group received 220 mg zinc sulfate, the second group were administered 5 mg folic acid, the third group received220 mg zinc sulfate plus 5 mg folic acid and the fourth group received placebo. All groups received medication or placebo daily for 8 weeks and were re-evaluated for laboratory tests.

Participants/Inclusion and exclusion criteria

1.Oligoovulation or / and anovulation; 2.Clinical symptoms (Ferriman-Gallwey score≥6 or Acne or Seborrhoeic) or biochemical hyperandrogenism; 3. Evidence of polycystic ovaries on ultrasound

Intervention groups

The final number of participants after considering the entry and exit criteria randomly and using a table of random numbers is divided into 4 groups and the first group 220 mg of zinc sulfate (containing 50 mg of zinc), the second group 5 mg of acid Folic acid, the third group will receive 220 mg of zinc sulfate (containing 50 mg of zinc) + 5 mg of folic acid and the fourth group, which is the control group, will receive a placebo daily for 8 weeks.

Main outcome variables

FBS; DHEAS; Testosterone; CRP; Cholesterol; LDL; HDL; TG; drug (folic acid + zinc sulfate)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200610047715N1**
Registration date: **2020-12-27, 1399/10/07**
Registration timing: **retrospective**

Last update: **2020-12-27, 1399/10/07**
Update count: **0**

Registration date

2020-12-27, 1399/10/07

Registrant information

Name
Elham Salari
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 34 3426 4005
Email address
esalarii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-12-01, 1397/09/10

Actual recruitment start date

2018-01-29, 1396/11/09

Actual recruitment end date

2019-01-29, 1397/11/09

Trial completion date

2019-01-30, 1397/11/10

Scientific title

The effect of zinc sulfate and folic acid on endocrine indices, CRP and lipid profile in women with polycystic ovary syndrome in 2017-18.

Public title

The effect of zinc sulfate and folic acid on endocrine indices, CRP and lipid profile in women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Oligoovulation or / and anovulation Clinical symptoms (Ferriman-Gallwey score≥6 or Acne or Seborrhoeic) or biochemical hyperandrogenism Evidence of polycystic ovaries on ultrasound

Exclusion criteria:

Hyperprolactinoma Thyroid disease Cardiovascular diseases Kidney-liver and neoplastic diseases Type 2 diabetes Pregnancy or breastfeeding Absorption disorders Use of drugs such as anti-diabetic drugs, anti-obesity drugs, diuretics, OCP, steroid and hormonal drugs (at least 3-6 months) and drugs that interfere with folic acid (perimetamine, aspirin, carbamazepine, chloramphenicol, chlorothiazide, conjugated estrogens, forge , Hydrochlorothiazide, Methotrexate, Phenytoin, Phenobarbital, Sulfamethoxazole, Salicylate)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table; to use a table of random numbers, the exact number of people in the community was first determined and coded in order. Then, to select sample people from the table, we randomly start from a point in the table in the direction of the row or column. The selected number is in fact the individual code of the community that is selected as the sample. We will continue to do this until a small number can be selected based on the number of sample people. After completing the sample size, the sampling work is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drugs and placebo were prepared in exactly the same drug form and packaged and coded in dark envelopes. As a result, the patient and the researcher were unaware of the group of people

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

No. 9, 53 Alley, Abuzar St., Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717715191

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

IR.RUMS.REC.1396.155

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

FBS

Timepoint

8 weeks after taking the drug

Method of measurement

BT4500

2

Description

Dehydroepiandrosterone sulfate

Timepoint
8 weeks after taking the drug

Method of measurement
ELISA reader

3

Description
Testosterone

Timepoint
8 weeks after taking the drug

Method of measurement
ELISA reader

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group received 220 mg of zinc sulfate (containing 50 mg of zinc) daily for 8 weeks

Category
Treatment - Drugs

2

Description
Intervention group: the second group received 5 mg of folic acid daily for 8 weeks

Category
Treatment - Drugs

3

Description
Intervention group: the third group received 220 mg of zinc sulfate (containing 50 mg of zinc) plus 5 mg of folic acid daily for 8 weeks.

Category
Treatment - Drugs

4

Description
Control group: this group received a placebo daily for 8 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rafsanjan Endocrine Clinic

Full name of responsible person
Mohammadreza Shafipour

Street address
Rafsanjan - Imam Ali Boulevard - Central Organization

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr. Ali Shamsizadeh

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellery for Research and Technology, Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Mohammadreza Shafipour

Position

Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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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