

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 received 220 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  $\geq 6$  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)

##### Phone

+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 $\geq$ 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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Rafsanjan

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**Postal code**

7717933777

**Phone**

+98 34 3428 0038

**Email**

mr.shafiepour@gmail.com

**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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alishamsy@gmail.com

**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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Ali Ibn Abi Talib Hospital in Rafsanjan

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Latest degree**

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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