

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### **Effect of Menaquinone supplementation on insulin resistance, lipid profile, anthropometric measurements, endocrine markers and oxidative stress in patients with polycystic ovary syndrome who will be referred to health centers of Shiraz University of Medical Sciences, 1396.**

#### **Protocol summary**

##### **Summary**

**Objectives:** The aim of current study is evaluation of the efficacy of 8-week oral supplementation of menaquinone on body mass index (BMI), waist circumference (WC), body composition, plasma level of fasting blood sugar (FBS), lipid profile, endocrine markers (including insulin, sex hormone binding globulin, dehydroepiandrosterone Sulfate, dihydrotestosterone) and malondialdehyde (MDA) in patients with polycystic ovary syndrome. **Design:** 84 patients participate in this study which is a double-blind and randomized placebo-control clinical trial. **Setting and conduct:** Patients in this study were randomly divided into two groups: 42 patients in case group receive 90 microgram menaquinone and 42 patients in control group receive placebo. Patients will be supplemented for 8 weeks. **Participants including major eligibility criteria:** Inclusion criteria: Suffering from polycystic ovary syndrome based on Rotterdam criteria; age between 18 to 40 ; absence of pregnancy or lactation; absence of antidiabetic, antihypertensive, antihyperlipidemic, anticoagulant treatment; absence of using metformin 2 months before entering the study and during the intervention; acute or chronic inflammation; absence of any current diet or supplement treatment; absence of antidiabetic, antihypertensive, antihyperlipidemic treatment; absence of using drugs effective on bone metabolism; any disease or physiological changes that requires special treatment; nonsmoker, nonalcoholic. **Exclusion criteria:** Failure to follow the intervention designing (not consuming dedicated supplement to the total amount less than 90% predicted or more than 3 days). **Interventions:** Taking 1 capsule containing menaquinone per day in case group and 1 capsule containing placebo daily in control group. **Main outcome measures:** Anthropometric indices, dietary intake, physical activity, hirsutism score, acne score,

biochemical parameters , and endocrine markers were measured at the baseline and after 8-week intervention. **Data analysis:** Data analysis will be carried out by using SPSS software version 16.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2017092836204N2**

Registration date: **2017-10-25, 1396/08/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2017-10-25, 1396/08/03

##### **Registrant information**

##### **Name**

Najmeh Hejazi

##### **Name of organization / entity**

Shiraz University of Medical Sciences, Faculty of Nutrition and Food Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 71 3725 1005

##### **Email address**

nhejazi@sums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Shiraz University of Medical Sciences

##### **Expected recruitment start date**

2017-06-22, 1396/04/01  
**Expected recruitment end date**  
2017-09-27, 1396/07/05  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Effect of Menaquinone supplementation on insulin resistance, lipid profile, anthropometric measurements, endocrine markers and oxidative stress in patients with polycystic ovary syndrome who will be referred to health centers of Shiraz University of Medical Sciences, 1396.

**Public title**  
Effect of Menaquinone supplementation on insulin resistance, lipid profile, anthropometric measurements, endocrine markers and oxidative stress in patients with polycystic ovary syndrome who will be referred to health centers of Shiraz University of Medical Sciences, 1396.

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
Inclusion criteria: Suffering from polycystic ovary syndrome based on Rotterdam criteria; age between 18 to 40 ; absence of pregnancy or lactation; absence of antidiabetic, antihypertensive, antihyperlipidemic, anticoagulant treatment; absence of using metformin 2 months before entering the study and during the intervention; acute or chronic inflammation; absence of any current diet or supplement treatment; absence of antidiabetic, antihypertensive, antihyperlipidemic treatment; absence of using drugs effective on bone metabolism; any disease or physiological changes that requires special treatment; nonsmoker, nonalcoholic.  
Exclusion criteria: Unwillingness to continue; any disease or physiological changes that requires special treatment; failure to follow the intervention designing (not consuming dedicated supplement to the total amount less than 90% predicted or more than 3 days).

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

**Gender**  
Female

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **84**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**

Parallel  
**Other design features**

## Secondary Ids

1  
**Registry name**  
-  
**Secondary trial Id**  
-  
**Registration date**  
empty

## Ethics committees

1  
**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Shiraz University of Medical Sciences  
**Street address**  
Shiraz University of Medical Sciences, Zand street  
**City**  
Shiraz  
**Postal code**  
**Approval date**  
2017-04-17, 1396/01/28  
**Ethics committee reference number**  
IR.SUMS.REC.1396.6

## 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**  
fasting blood sugar  
**Timepoint**  
Before and after intervention  
**Method of measurement**  
auto analyser

2  
**Description**  
Dehydroepiandrosterone Sulfate (DHEAS)  
**Timepoint**  
Before and after intervention  
**Method of measurement**

ELISA kit

## Secondary outcomes

### 1

#### Description

total testosterone

#### Timepoint

Before and after intervention

#### Method of measurement

ELISA kit

### 2

#### Description

Malondialdehyde (MDA)

#### Timepoint

Before and after intervention

#### Method of measurement

Spectrophotometry

### 3

#### Description

dihydrotestosterone (DHT)

#### Timepoint

Before and after intervention

#### Method of measurement

ELISA kit

### 4

#### Description

Sex Hormone Binding Globulin (SHBG)

#### Timepoint

Before and after intervention

#### Method of measurement

ELISA kit

### 5

#### Description

lipid profile (TG, Cholesterol, HDL, LDL)

#### Timepoint

Before and after intervention

#### Method of measurement

auto analyser

### 6

#### Description

fasting insulin

#### Timepoint

Before and after intervention

#### Method of measurement

ELISA kit

## Intervention groups

### 1

#### Description

Intervention group: 1 capsule containing 90 micrograms of menaquinone per day for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 1 placebo capsule containing avelil per day for 8 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghadir Mother and Child Hospital, Infertility Clinic

##### Full name of responsible person

Dr. Bahia Namavar Jahromi

##### Street address

At the entrance to Golshan town, Imam Reza blvd

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Basir Hashemi

##### Street address

Office of Research and Technology, Seventh Floor, Central Building of Shiraz University of Medical Sciences, Zand Street

##### City

Shiraz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

#### 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**  
Shiraz University of Medical Sciences, Faculty of  
Nutrition and Food Sciences  
**Full name of responsible person**  
Firoozeh Tarkesh  
**Position**  
MSc student  
**Other areas of specialty/work**  
**Street address**  
Department of Nutrition and Food Science,  
Fatholmobin alley, Razi blvd  
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firoozeh\_tarkesh@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences, Faculty of  
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**Full name of responsible person**  
Najmeh Hejazi  
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Ph.D. in Nutritional Sciences, Assistant Professor  
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Nhejazi@sums.ac.ir  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences, Faculty of  
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**Full name of responsible person**  
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**Email**  
firoozeh\_tarkesh@yahoo.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*