# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 2026

## Effect of Menaquinone supplementation on insulin resistance, lipid profile, anthropometric measurments, 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 patiens in case group recieve 90 microgram menaquinone and 42 patients in control group recieve 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 ; absecnce 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). Inteventions: 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, hirsuitism 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 measurments, 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 measurments, 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 ; absecnce 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**
Befor 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 avesil 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 Reze 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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*