

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 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
City
Shiraz
Postal code
Phone
+98 71 3725 1001
Fax
Email
firoozeh_tarkesh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences, Faculty of
Nutrition and Food Sciences
Full name of responsible person
Najmeh Hejazi
Position
Ph.D. in Nutritional Sciences, Assistant Professor
Other areas of specialty/work
Street address
Department of Nutrition and Food Science,
Fatholmobin alley, Razi blvd
City
Shiraz
Postal code

Phone
+98 71 3725 1001
Fax
Email
Nhejazi@sums.ac.ir
Web page address

Person responsible for updating data

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
City
Shiraz
Postal code
Phone
+98 71 3725 1001
Fax
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