Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect of Menaquinone(MK-7) supplementation on deppression status, fasting blood sugar and serum vitamin K level in patients with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is evaluation of the efficacy of 8-week supplementation with Menaquinone(MK-7) on deppression status, fasting glucose and serum vitamin K level in patients with polycystic ovary syndrome.

Design

This double-blinded, Randomised, placebo-controlled, parallel group clinical trial will be carried out on 84 patients suffering from polycystic ovary syndrome. In this study patients will be selected based on inclusion criteria and they will be followed for 8 weeks. Demographic information and depression questionnaires will be completed by each patient. Also, 5 cc of fasting blood (to determine the level of fasting serum glucose and serum vitamin K) will be collected. In the next stage, patients will be divided into two groups of Menaquinone-7 and placebo through block randomization. The final visit of patients is going to be at the end of the trial and 5 cc of fasting blood will bw collected for the second time and depression questionnaires will be completed for the second time.

Settings and conduct

Patient recruitment and assessments in this double-blinded study will be executed in Ghadir hospital. Vitamin K and placebo capsules will be packaged in the similar boxes by an individual other than the researcher, therefore both researchers and patients won't be aware of the contents of the boxes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Polycystic ovary syndrome; Being in the age range of 18-40 years; The desire to participate in the study. Non inclusion criteria: Suffering from any Acute or chronic inflammatory disease; Using any medication or supplements

Intervention groups

The case group (42 patients) will receive one capsule containing 90 micrograms of menaquinone daily and the control group (42 patients) will receive a placebo capsule daily for 8 weeks.

Main outcome variables

fasting blood sugar-depression status-serum vitamin K

General information

Reason for update

The time period of recruiting patients was mistakenly written in the first version.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170916036204N5**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **retrospective**

Last update: **2020-11-14, 1399/08/24**
Update count: **1**

Registration date

2018-06-06, 1397/03/16

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

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(MK-7) supplementation on deppression status, fasting blood sugar and serum vitamin K level in patients with polycystic ovary syndrome

Public title

effect of Menaquinone(MK-7) supplementation on deppression status in patients with polycystic ovary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Suffering from polycystic ovary syndrome based on Rotterdam criteria; Age between 18 to 40

Exclusion criteria:

Unwillingness to participate Any disease or physiological changes that requires special treatment Pregnancy or lactation Using antidiabetic, antihypertensives, antihyperlipidemics or anticoagulant treatment Using metformin 2 months before entering the study and during the intervention; Acute or chronic inflammation Being smoker or/and alcoholic. Using drugs effective on bone metabolism Any current diet or supplement treatment Using oral contraceptives

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be classified into placebo and target groups with block randomization and Random allocation methods.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants in this study are unaware about their grouping because the package, label, and appearance of Menaquinone and placebo capsules are quite similar. Vitamin K and placebo capsules will be packaged by an individual other than the researcher in the same boxes, therefore researchers are not aware of the contents of the boxes too.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

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

Province

Fars

Postal code

7134814336

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.SUMS.REC.1397.102

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

Depression score in BECK questionnaire

Timepoint

Before and after the intervention

Method of measurement

BECK depression questionnaire

Secondary outcomes

1

Description

Serum vitamin K level

Timepoint

Before and after the intervention

Method of measurement

ELISA kit

2

Description

Fasting Blood Sugar

Timepoint

Before and after intervention

Method of measurement

auto analyser

Intervention groups

1

Description

Intervention group: A capsule containing 90 µg of menaquinone daily for 8 weeks

Category

Treatment - Drugs

2

Description

control group: A capsule containing avesil daily 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

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7144995377

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enghelab@sums.ac.ir

Web page address

http://shirazmch.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Firoozeh Tarkesh

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Shiraz University of Medical Sciences

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Najmeh Hejazi

Position

Ph.D. in Nutrition Sciences, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable