

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of magnesium and vitamin E supplementation on hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim

The effect of magnesium and vitamin E supplementation on hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

Design

Clinical trial with control group, with parallel groups, randomized, phase 3 on 72 patients. Block method was used for randomization

Settings and conduct

A randomized clinical trial study was performed in Golestan province, Gorgan, Taleghani Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria : Definitive diagnosis of PCOS based on Rotterdam criteria - Age 18 to 40 years
Exclusion criteria : - Pregnancy - Adrenal hyperplasia - Androgen-secreting tumors - Hyperprolactinemia - Thyroid dysfunction - Diabetes - Receiving antioxidant and anti-inflammatory supplements 3 months before the start of the study

Intervention groups

The intervention group received 250 mg / day magnesium oxide (Twenty First Century Pharmaceutical Company, AZ, USA) plus 400 international units of vitamin E per day (Zahravi Pharmaceutical Company, Tabriz, Iran) for 12 weeks.

Main outcome variables

The effect of magnesium and vitamin E supplementation on hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220102053603N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **prospective**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Maryam Kamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

ykml@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of magnesium and vitamin E supplementation on hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

Public title

The effect of magnesium and vitamin E supplementation on hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome referred to Nahal Infertility Treatment Center, Gorgan in 2021

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of PCOS based on Rotterdam criteria
Age 18 to 40 years

Exclusion criteria:

Pregnancy Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes
Receiving antioxidant and anti-inflammatory supplements 3 months before the start of the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **38**

The study population included all women with PCOS referred to Nahal Infertility Treatment Center in Gorgan, Shahid Sayad Shirazi Hospital in 2021

Randomization (investigator's opinion)

Randomized

Randomization description

We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 4. From the following blocks, first select 1 by accident and divide the samples into two groups according to the order and fill the blocks A for intervention and B for placebo B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients and physicians evaluating the designed interventions in the study or the post-project outcomes will not be aware of the group in which the patient is being examined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences,
Gorgan, Shastkola road, Philosophical Higher Education Complex

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.GOUMS.REC.1400.252

Health conditions studied

1

Description of health condition studied

Hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Hormonal status and biomarkers of inflammation and oxidative stress

Timepoint

12 weeks after taking the supplement

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 250 mg magnesium oxide per day (Twenty First Century Pharmaceutical Company, AZ, USA) plus 400 international units of vitamin E per day (Zahravi Pharmaceutical Company, Tabriz, Iran) for 12 weeks

Category

Treatment - Drugs

2**Description**

Control group: They received placebo (Barij Essence Pharmaceuticals, Kashan, Iran) for 12 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Hospital

Full name of responsible person

Dr. Mahbobeh Azadehrah

Street address

Philosophical Higher Education Complex, Shast Kola Road, Gorgan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Gorgan University of Medical Sciences

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Use of data to complete the research process on the effects of magnesium and vitamin E supplementation on hormonal status and biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

From where data/document is obtainable

Contact the author of the article responsible for the research project data.

What processes are involved for a request to access data/document

Contact the author of the article responsible for the research project data. Specify the type of results requested.

Comments