

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effects of vitamin D supplementation on hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with polycystic ovary syndrome candidates for IVF

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in patients with polycystic ovary syndrome candidates for IVF

Design

Study design: Randomized double-blind placebo-controlled trial, All participants will have stratified randomization according to BMI (<25 and ≥ 25 kg/m²) and age (<30 and ≥ 30 y). Then, participants in each block will be randomly allocated into two groups. Randomization will be done by the use of computer software.

Settings and conduct

Among patients with polycystic ovary syndrome candidates for IVF referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. At the beginning and the end of the intervention: 8 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome candidates for IVF aged 18 to 40 years.
Exclusion criteria: Individuals with neoplastic disorders, cardiovascular diseases, malabsorptive disorders, and current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications.

Intervention groups

Intervention group: 50000 IU vitamin D3 (Zahravi, Tabriz, Iran), weekly, for 8 weeks orally. Control group: Placebo

(Barij Essence, Kashan, Iran), weekly, for 8 weeks orally.

Main outcome variables

Outcomes: Total testosterone (primary outcome) and biomarkers of inflammation, oxidative stress and gene expression related to inflammation (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N53**

Registration date: **2019-03-29, 1398/01/09**

Registration timing: **retrospective**

Last update: **2019-03-29, 1398/01/09**

Update count: **0**

Registration date

2019-03-29, 1398/01/09

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-17, 1397/09/26

Expected recruitment end date

2019-01-16, 1397/10/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of vitamin D supplementation on hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with polycystic ovary syndrome candidates for IVF

Public title

Effect of vitamin D supplementation in the treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Patients with polycystic ovary syndrome candidates for IVF Individuals aged 18 to 40 years.

Exclusion criteria:

Exclusion criteria: Individuals with neoplastic disorders cardiovascular diseases malabsorptive disorders current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥ 25 kg/m²) and age (<30 and ≥ 30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Kosar clinic, who is not

involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

1771844351

Approval date

2018-12-16, 1397/09/25

Ethics committee reference number

IR.ARAKMU.REC.1397.246

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**

Total testosterone

Timepoint

En At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2**Description**

SHBG

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Expressed levels of TNF- α gene

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

PCR

7

Description

Expressed levels of IL-1 gene

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

PCR

8

Description

Expressed levels of IL-8 gene

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: 50000 IU vitamin D every weeks (Zahravi, Tabriz, Iran), for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran) every weeks, for 8 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Kosar Clinic

Full name of responsible person

Mehri Jamilian

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Emam Khomeyni Avenue, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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Sardasht Avenue, Vice chancellor for research, Arak
University of Medical Sciences
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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

Arak 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available