

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of inofolic supplementation in combination with probiotics and vitamin D on ovarian response and metabolic profiles in women with polycystic ovary syndrome candidate for In Vitro Fertilization

Protocol summary

Study aim

Determining the effect of inofolic supplementation and its combination with probiotics and vitamin D on ovarian response and metabolic profiles in women with polycystic ovary syndrome (PCOS) candidate for In vitro fertilization (IVF)

Design

Randomized clinical trial, double blind, controlled with placebo, parallel, single center

Settings and conduct

Among patients with PCOS candidate for IVF referred to Mahdie Clinic affiliated to Shahid Beheshti University of Medical Sciences, 120 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.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women with PCOS according to the Rotterdam criteria, In Vitro Fertilization candidate, Age 45-30 years, No smoking, Male reproductive health

Intervention groups

Intervention group 1: Inofolic Sachet ; Inositol 2gr, twice a day(Teb mofid nikan)plus probiotic Capsule (1.8 ×10⁹ CFU/capsule),One capsule per day(Takgene Zist) plus Vitamin D Capsule; 4000 IU ,One capsule per day(Daana). Intervention group 2: Inofolic Sachet ; Inositol 2gr, twice a day plus probiotic Capsule (1.8 ×10⁹ CFU/capsule),One capsule per day plus Vitamin D placebo; Sunflower oil, One capsule per day (Daana) .Intervention group 3: Inofolic Sachet ; Inositol 2gr, twice a day plus Probiotic placebo ;starch, One capsule per day(Takgene Zist) plus Vitamin D Capsule; 4000 IU ,One capsule per day. Control group: Inofolic Sachet; Inositol 2gr, twice a day plus Probiotic placebo; starch, One capsule per day plus Vitamin D placebo; Sunflower oil,

One capsule per day for 8 weeks orally

Main outcome variables

Anti-Mullerian hormone, high-sensitivity C-reactive protein, Beck score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N34**

Registration date: **2023-01-23, 1401/11/03**

Registration timing: **prospective**

Last update: **2023-01-23, 1401/11/03**

Update count: **0**

Registration date

2023-01-23, 1401/11/03

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inofolic supplementation in combination with probiotics and vitamin D on ovarian response and metabolic profiles in women with polycystic ovary syndrome candidate for In Vitro Fertilization

Public title

The effects inofolic supplementation, probiotic and vitamin D in polycystic ovary syndrome women candidate for In Vitro fertilization

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with Polycystic Ovary Syndrome (PCOS) according to the Rotterdam criteria In Vitro Fertilization (IVF) candidate Age 45-30 years No smoking Male reproductive health

Exclusion criteria:

Uncontrolled thyroid disorder Diagnosis of severe depression

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The people who entered the study based on the inclusion and exclusion criteria will be randomly assigned to one of the four control or intervention groups within each block using the random block method. The size of each block will be equal to four, eight or twelve samples, which will be applied to people based on a random permutation of treatments after completing each block. Blocks and permutations within each block will be created using the agricolae package in R software and using a specific seed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Coding and similar packaging will be used for blinding. Therefore, the physician, patient, researcher and statistical analyzer are blind to the content of the packages. At the end of the study and analysis of data, decoding will be done. Another person at the clinic, who is not involved in the trial and not aware of assignments,

will assign numbered bottles of capsules to the participants. Placebos capsules are completely identical with supplements in terms of their appearance, color, shape, size, and packaging.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Medical and Dental Faculties of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Qotbe Ravandi Boulevard, Kashan, Phone number :03155542999

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2022-11-06, 1401/08/15

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.158

Health conditions studied**1****Description of health condition studied**

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2**Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Anti Mullerian Hormone (AMH)

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

ELISA

2

Description

High Sensitivity- C Reactive Protein (hs-CRP)

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

ELISA

3

Description

Beck score

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Beck questionnaire

Secondary outcomes

1

Description

Fasting plasma glucose

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Enzymatic Kits with BT-3000

2

Description

Insulin

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

ELISA

3

Description

HOMA-IR

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Calculated with standard formula

4

Description

Nitric oxide

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Photospectrometry

5

Description

Total Anti Oxidant (TAC)

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Photospectrometry

6

Description

Glutathion

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Photospectrometry

7

Description

Malondialdehyde

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Photospectrometry

8

Description

Peroxisome proliferator-activated receptor gamma (PPAR- γ) gene expression

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

RT-PCR

9

Description

low Density Lipoprotein Receptor (LDLR) gene expression

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

RT-PCR

10

Description

Tumour necrosis factor α (TNF α) gene expression

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

RT-PCR

11**Description**Interferon gamma (IFN- γ) gene expression**Timepoint**

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

RT-PCR

12**Description**

Vascular endothelial growth factor (VEGF) gene expression

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

RT-PCR

13**Description**

Anxiety

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Beck questionnaire

14**Description**

Sleep Quality

Timepoint

Before the intervention and after 8 weeks from the start of the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

15**Description**

Ovarian response

Timepoint

8 weeks after the start of the intervention

Method of measurement

Optical microscope

Intervention groups**1****Description**

Intervention group 1: Inofolic Sachet ; Inositol 2gr, twice a day(Teb mofid nikan,Alborz, Iran) plus probiotic Capsule;Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium langum, Bifidobacterium lactis (1.8 \times 10⁹ CFU/capsule), One capsule per day(Takgene

Zist ,Tehran, Iran) plus Vitamin D Capsule; 4000 IU ,One capsule per day(Daana ,Tabriz ,Iran) for 8 weeks orally

Category

Treatment - Drugs

2**Description**

Intervention group 2: Inofolic Sachet ; Inositol 2gr, twice a day(Teb mofid nikan, Alborz, Iran) plus probiotic Capsule;Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium langum, Bifidobacterium lactis (1.8 \times 10⁹ CFU/capsule), One capsule per day(Takgene Zist ,Tehran, Iran) plus Vitamin D placebo (Daana ,Tabriz ,Iran), One capsule per day for 8 weeks orally

Category

Treatment - Drugs

3**Description**

Intervention group 3: Inofolic Sachet ; Inositol 2gr, twice a day(Teb mofid nikan ,Alborz,Tehran) plus Probiotic placebo ;starch, One capsule per day(Takgene Zist ,Tehran, Iran) plus Vitamin D Capsule; 4000 IU ,One capsule per day(Daana ,Tabriz ,Iran) for 8 weeks orally

Category

Treatment - Drugs

4**Description**

Control group: Inofolic Sachet; Inositol 2gr, twice a day(Teb mofid nikan ,Alborz, Iran) plus Probiotic placebo; starch (Takgene Zist ,Tehran, Iran), One capsule per day plus Vitamin D placebo (Daana ,Tabriz,Iran), One capsule per day for 8 weeks orally

Category

Placebo

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

Infertility Clinic of Mahdia Hospital

Full name of responsible person

Zahra Heidar

Street address

Shishagar Khane Alley, , Fedayian Islam St, Shush Square

City

Tehran

Province

Tehran

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1185817311

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+98 21 5506 2628

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mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

School of Medicine, Qotbe Ravandi Boulevard,
Kashan,Iran

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hamidi_gh@kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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

Mohsen Taghizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information is kept confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

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

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main outcomes can be shared after the release of the results.

When the data will become available and for how long

6 months after publishing the paper .

To whom data/document is available

Researchers working in academic and research institutions.

Under which criteria data/document could be used

Using data to complete further studies.

From where data/document is obtainable

Dr Mohsen Taghizadeh, Kashan university of medical sciences

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

The data can be shared after the researcher's request and evaluating their research evidence.

Comments