Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Isfehan
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 (TNFα) 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 ×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 ×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
Postal code
1185817311
Phone
+98 21 5506 2628
Email
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
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 0021
Email
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
Street address
School of Medicine, Qotbe Ravandi Boulevard, Kashan,Iran
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5533 3213
Email
taghizadeh_m@kaums.ac.ir

Person responsible for scientific 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
Street address
School of Medicine, Qotbe Ravandi Boulevard, Kashan,Iran
City
kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5533 3213
Email
taghizadeh_m@kaums.ac.ir

Person responsible for updating data

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
Street address
School of Medicine, Qotbe Ravandi Boulevard, Kashan,Iran
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5533 3213
Email
taghizadeh_m@kaums.ac.ir

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