

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of Turmeric tablet on serum and follicular fluid inflammatory and oxidative stress indicators in women with polycystic ovary syndrome undergoing infertility treatment

Protocol summary

Study aim

Determining the effect of turmeric tablets on inflammatory indices and oxidative stress of blood and follicular fluid of women with polycystic ovary syndrome undergoing infertility treatment.

Design

A clinical trial with one intervention groups and a control group, three blind strains, phase is conducted on 60 patients. For randomization, randomization is done through the quadruple block method and the block method using the seal envelope site.

Settings and conduct

Infertility Clinic of Akbar Abadi Hospital conducts randomization method on 60 patients. The intervention and placebo groups used 3 tablets of turmeric and placebo daily for 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women undergoing IVF infertility treatment - Iranian origin - married - Ages 18-40 years
Exclusion criteria: 1) Consumption of food and pharmaceutical supplements 2) Adhering to a special diet such as vegetarianism 3) Women with a history of infertility with simultaneous diagnosis of polycystic ovary syndrome and endometriosis 4) Hepatic and biliary disorders 5) under treatment with anticoagulant drugs 6) Active gastric ulcer 7) Having a history of allergy to turmeric or its products 8) Slimming diets 9) Athletes or special sports
Exit criteria: -The occurrence of an allergy to turmeric during the study, which leads to discontinuation of the treatment as determined by a specialist doctor. - Failure to take the medicine correctly for a maximum of two consecutive days or 3 alternate days per week - Discontinuation of infertility treatment before puncture for any possible reason

Intervention groups

The intervention group used 3 tablets of 500 mg of turmeric daily for 6 weeks, and the placebo group used 3

tablets containing (placebo) daily.

Main outcome variables

inflammatory indicators, Oxidative stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100713004364N2**

Registration date: **2023-09-11, 1402/06/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-11, 1402/06/20**

Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Leila Amini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-23, 1402/04/02

Expected recruitment end date

2024-09-23, 1403/07/02

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Turmeric tablet on serum and follicular fluid inflammatory and oxidative stress indicators in women with polycystic ovary syndrome undergoing infertility treatment

Public title
Investigating the effect of Turmeric tablet on serum and follicular fluid inflammatory and oxidative stress indicators in women with polycystic ovary syndrome undergoing infertility treatment

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
Women undergoing IVF infertility treatment Iranian origin
Ages 18-40 years married Body mass index below 30 kg/m²
Exclusion criteria:
1) Consumption of food and pharmaceutical supplements
2) Adhering to a special diet such as vegetarianism 3)
Women with a history of infertility with simultaneous diagnosis of polycystic ovary syndrome and endometriosis 4) Hepatic and biliary disorders 5) under treatment with anticoagulant drugs 6) Active gastric ulcer 7) Having a history of allergy to turmeric or its products 8) Slimming diets 9) Athletes or special sports

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyst

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A study is a three-blind randomized controlled trial in which the sampling will be continuous and the allocation of samples to the study groups will be random. Allocation of samples into two intervention and placebo groups will be done randomly and through the quadruple block method. The method of block classification is determined by someone other than the researcher using the sealed envelope site, and the blocks are placed in opaque numbered envelopes.

Blinding (investigator's opinion)
Triple blinded

Blinding description
It is a three-blind randomization (researcher, people

participating in the research, and a statistician).

Placebo
Used

Assignment
Parallel

Other design features

Secondary IDs
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Nursing & Midwifery faculty, Yasemi Ave, Valiasr St
City
Tehran
Province
Tehran
Postal code
۱۹۹۶۷۱۳۸۸۳

Approval date
2023-07-31, 1402/05/09

Ethics committee reference number
IR.IUMS.REC.1402.370

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
Women Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
"Changes in inflammatory indices in women with polycystic ovary syndrome"

Timepoint
6 weeks after starting to take turmeric tablets

Method of measurement
Inflammatory indices in this study mean the

measurement of C-reactive protein (in milligrams per liter), interleukin-6 (ELISA method) and the ratio of neutrophils to lymphocytes in the serum and follicular fluid of patients. IL-6: Interleukin 6 Human Platinum ELISA kit with ELISA method; It can be measured with a sensitivity of 0.92 pg/ml and with a normal range of results: 1-100 pg/ml. CRP: Bionik CRP biochemistry kit made in Iran with photometric method and normal range of results: values up to 6 mg/L can be measured. Neutrophil to lymphocyte ratio: Sysmex model N-21KX machine is used for cell counting and to determine the percentage of neutrophils and lymphocytes, visual method or light microscope and Giemsa staining are used.

2

Description

and "Changes in oxidative stress indices in women with polycystic ovary syndrome"

Timepoint

6 weeks after starting to take turmeric tablets

Method of measurement

Oxidative stress indicators: Oxidative stress indicators in this research mean the measurement of malondialdehyde MDA (in micromolar per liter), total antioxidant capacity TAC and reactive oxygen radical ROS (milliunits per milliliter) in serum and follicular fluid of patients . MDA: It is measured using a 96-piece Well-plate kit made in Iran, Kia Biot Company, with a fluorimetric method that has a normal dynamic range: 20-100 µm. TAC: It is measured using a 96-piece Clean photometric plate well kit made in Iran, Kia Zeet company, with the Kuprak method, which has a dynamic range of 40-400 nmol/ml. ROS: It is measured by flow cytometry and fluorimetry using a kit of 96 Well Sterile Fluorimetric plates made in Iran, Kia Life Company. The fluorophore can be read at a wavelength of 525-485 Em/Ex=nm in plate fluorimetry or flow cytometry.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Turmeric tablet containing 450 mg of turmeric rhizome powder and 50 mg of turmeric extract, which is standardized by Dineh Pharmaceutical Company with drug registration number 7796008783541035, based on 5.47 mg of curcumin. 3 tablets are given daily to the internal group for 6 weeks.

Category

Prevention

2

Description

Control group: Placebo tablets containing 500 mg of maltodextrin are used 3 times a day by Dineh

Pharmaceutical Company for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Shahid Akbarabadi Hospital

Full name of responsible person

Mahboubeh Karimi Majd

Street address

No. 31, Ghaem alley , Ghaem Ave, Railway Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Kiwani

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Office of Vice President for International Affairs, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran 14496-14535, IRAN

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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

Iran University of Medical Sciences

Proportion provided by this source

80

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

2

Sponsor

Name of organization / entity
Dineh Pharmaceutical Company of Iran
Full name of responsible person
Mahan Ebrahimi Qajar
Street address
No. 23, Shahid Jafarzadegan St., between Fasat and Nusrat, North Kargar St
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Email
info@dinehiran.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Dineh Pharmaceutical Company of Iran

Proportion provided by this source

5

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

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Iran University of Medical Sciences
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Leila Amini
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Assistant Professor
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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