Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative assessment of the effect of complementary treatment with Cinnamon and Turmeric capsules on Polycystic Ovarian Syndrome: A triple blind clinical trial

Protocol summary

Study aim

Determining the therapeutic effect of cinnamon and turmeric supplements in patients with polycystic ovary syndrome

Design

The sampling method is available among women with polycystic ovary syndrome aged 18 to 45 years referred to Urmia educational and treatment centers. Patients will be divided into four groups (recipients of turmeric supplement capsules, cinnamon supplement, turmeric and cinnamon supplement, and control) using block randomization method. A total of 160 samples will be selected.

Settings and conduct

For groups, group 1 turmeric (500 mg capsule) twice daily, group 2 cinnamon (500 mg capsule) twice daily, group 3 cinnamon and turmeric 1000 mg capsule) twice daily and group 4 placebo twice, respectively. The interventions will be performed for each of the patients for three months (12 weeks). Follow-ups will be done by phone and weekly, as well as once a month as presence on site.

Participants/Inclusion and exclusion criteria

inclusion criteria Age 18 to 45 years Diagnosis of PCOS by a gynecologist No pregnancy at now No receiving infertility treatment Do not take hormonal drugs at the last 3 months Do not take any medication or nutritional supplements Interval of more than 4 years from the beginning of menarche Absence of severe underlying diseases

Intervention groups

Group 1 turmeric (500 mg capsules) twice daily Group 2 cinnamon (500 mg capsules) twice daily Group 3 cinnamon and turmeric 1000 mg capsules) twice daily Group 4 placebo twice daily.

Main outcome variables

Primary outcomes (irregular menstrual frequency, hirsutism, serum testosterone levels, FAI index and polycystic ovary frequency) and secondary outcomes (FSH, LH, FBS, HOMA-IR and malondialdehyde).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201022049117N1**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Leili Rahmatnezhad

Name of organization / entity

The University of Tarbiat Modares

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-30, 1399/09/10

Expected recruitment end date

2021-12-01, 1400/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of the effect of complementary treatment with Cinnamon and Turmeric capsules on Polycystic Ovarian Syndrome: A triple blind clinical trial

Public title

Comparative assessment of the effect of complementary treatment with Cinnamon and Turmeric capsules on Polycystic Ovarian Syndrome: A triple blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 45 years Diagnosis of PCOS by a gynecologist (according to clinical, laboratory, and imaging symptoms) Not pregnant now Failure to receive infertility treatment Do not take hormonal drugs or any medication for at least the last 3 months Do not take any medication or nutritional supplements More than 4 years after the onset of menarche Absence of severe underlying disease

Exclusion criteria:

Do not take the desired drugs for at least 7 days a month The unwillingness of the participant to continue the participation for any reason Occurrence of any adverse or intolerable complications during the study due to the patient's complaint, or physician's diagnosis Occurrence of pregnancy

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of participants in study groups will be done by block-randomized randomization using Random allocation software, so that according to the groups under study (4 groups) 8 blocks of AABBCCDD will be formed and then all possible combinations of It will be listed and a code will be assigned to each of these combinations, then 20 blocks will be considered using a random number, depending on the sample size (160) and the volume of the blocks (8). The whole process will be performed under the supervision of an epidemiologist.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This will be a triple-blind study, so that the participants, as well as researcher and analyzer of the results of the study will be unaware . For this purpose, the form of supplement capsules and placebo capsules are similar and the participants and the researcher are unaware of its content. In addition, the analyzer will not know which sample received which type of treatment. After completing the research and performing the relevant analyzes, the study groups will be asked and identified from the source of supply of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tehran Jalal AleAhmad Nasr

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.MODARES.REC.1399.109

Health conditions studied

1

Description of health condition studied

Polycystic Ovarian Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

irregular menstrual frequency

Timepoint

At the beginning of the study and after 12 weeks

Method of measurement

History, clinical and paraclinical examinations

2

Description
hirsutism
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
History, clinical and paraclinical examinations

3

Description
serum testosterone levels
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
History, clinical and paraclinical examinations

4

Description
Serum FAI (Free Androgen Index)
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
History, clinical and paraclinical examinations

5

Description
polycystic ovary
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
History, clinical and paraclinical examinations

Secondary outcomes

1

Description
HOMA-IR (Homeostasis Model Assessment - Insulin resistance)
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
Paraclinical examinations

2

Description
FBS (Fasting blood sugar)
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
Paraclinical examinations

3

Description
(MDA) Malone di aldehyde
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
Paraclinical examinations

4

Description
FSH (Follicle-stimulating Hormone)
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
Paraclinical examinations

5

Description
LH (luteinizing hormone)
Timepoint
At the beginning of the study and after 12 weeks
Method of measurement
Paraclinical examinations

Intervention groups

1

Description
Patients will be divided into four study groups (recipients of turmeric supplement capsules, cinnamon supplement, turmeric and cinnamon supplement, and control). A total of 160 samples will be randomly available from among women with PCOS. The capsules will be prepared in Urmia School of Pharmacy under the supervision of a respected pharmacist consultant and will contain 1000 mg of starch as a carrier. The capsules will not differ in weight, shape, color and smell, and they will be taken orally twice a day. The first intervention group will include turmeric (500 mg capsule) twice a day (morning and night). As drug therapy, medroxyprogesterone and metformin tablets will be prescribed to all patients undergoing concomitant supplements. How to prescribe medication under the supervision of a specialist doctor in the form of medroxyprogesterone tablets 5 mg once a day for ten days in the last ten days of the menstrual cycle, and metformin tablets 500 mg twice a day. The mentioned interventions will be performed for each of the subjects for three months (12 weeks). Follow-ups will be done by phone and weekly, as well as once a month in person and simultaneously through social networks. To assess patients' adherence to the treatment regimen, they will be asked to bring their medications with each visit and the number of unused capsules will be counted. While following up, the number of people who received the intervention and those who did not receive the intervention or received it irregularly will be determined by stating the reason, and those who did not receive the intervention or received it irregularly, They will be excluded from the study (failure to take the desired drugs for at least 7 days a month, according to studies, will lead to exclusion from the study), but will be included in the analysis with the intention of treatment.
Category
Treatment - Other

2

Description
Intervention group: Cinnamon (500 mg capsule) twice a day (morning and night)
Category
Treatment - Drugs

3

Description
Intervention group: Combination of cinnamon and turmeric capsules 1000 mg twice a day (morning and night)
Category
Treatment - Drugs

4

Description
Control group: Placebo capsules twice a day (morning and night)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid motahari hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Tarbiat Modares University
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
The University of Tarbiat Modares
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Leili Rahmatnezhad
Position
Ph.D student
Latest degree
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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