Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the Effect of Clove Oil (Syzygium aromaticum) and Oral Contraceptive LD on Improvement of Clinical and Paraclinical Parameters of Polycystic Ovarian Syndrome (PCOS): A Triple Blind Randomized Controlled Trial

Protocol summary

Study aim

Comparison of the effect of clove oil with combined oral contraceptives (COCs) on the improvement of clinical and paraclinical symptoms of polycystic ovary syndrome.

Design

The controlled clinical trial, with two parallel arms, triple-blind, randomized, phase 3 on 64 patients. RAS (Random Allocation Software) will be used for randomization.

Settings and conduct

Sixty women aged 18 to 45 referring to the clinics of Tabriz University of Medical Sciences and suffering from polycystic ovary syndrome, will be randomly assigned into two intervention groups of clove oil recipient and control (combined oral contraceptive) using block randomization method with a 1:1 allocation ratio. Both drugs will be completely identical to their placebo in terms of shape, color, and weight. The researcher, the patient, the data analyst, and the outcome examiner will be blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of PCOS according to Rotterdam criteria, age 18 to 45 years, literacy, body mass index between 18.5 and 30, not using hormonal contraceptives Exclusion criteria: Relative and absolute contraindications to LD pills, suffering from amenorrhea, undergoing infertility treatment at the time of the study, previous surgery on one or both ovaries, allergy to clove oil, disorders that cause hyperandrogenism, thyroid disorders

Intervention groups

The intervention group, every 28 days will receive one soft capsule of clove oil daily and one placebo tablet of COCs for 21 days and 7 days without using it for three cycles, and the control group, every 28 days will receive one placebo soft capsule of clove oil and one tablet COCs daily for 21 days and 7 days without taking it for three cycles. Original drugs will be identical in shape, color, and weight to their placebo counterparts.

Main outcome variables

Changes in serum DHEA levels; total testosterone; Average hirsutism score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N14**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2023-06-03, 1402/03/13**
Update count: **0**

Registration date

2023-06-03, 1402/03/13

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1333 9151

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10

Expected recruitment end date

2024-11-30, 1403/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Clove Oil (Syzygium aromaticum) and Oral Contraceptive LD on Improvement of Clinical and Paraclinical Parameters of Polycystic Ovarian Syndrome (PCOS): A Triple Blind Randomized Controlled Trial

Public title

Comparing the Effect of Clove Oil and Oral Contraceptive LD on Improvement of Clinical and Paraclinical Parameters of Polycystic Ovarian Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The diagnosis of PCOS according to the Rotterdam criteria Age 18 to 45 years Being literate BMI between 18.5 and 30 Not using hormonal contraceptives or any other type of hormonal medication currently and during the last three months

Exclusion criteria:

Relative and absolute contraindications of LD pills (having blood pressure above 140/90, smoking and alcohol consumption, pregnancy or breastfeeding, alcohol consumption, smoking, suspicion of breast cancer, coronary heart disease, endometrial carcinoma, etc.) Women suffering from amenorrhea Women undergoing infertility treatment at the time of study Previous surgery on one or both ovaries Allergy to clove oil Disorders that cause hyperandrogenism (having Cushing's syndrome, adrenal hyperplasia, androgen-producing tumors, etc.) Thyroid disorders

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible people will be allocated into two intervention groups (receiving clove oil) and control (receiving COCs) using the random block method with the size of blocks of four and six with an allocation ratio of 1:1. The allocation sequence will be generated by the assistant of the researcher using RAS (Random Allocation Software). Medicines will be placed inside opaque packs numbered sequentially from 1 to 64 containing three pairs of packets. The intervention will consist of three cycles of 4 weeks. Each person will be given two packets in each cycle, one containing 28 soft capsules of clove oil or its placebo and the other containing 21 LD tablets or its placebo. They will be prepared according to the allocation sequence by a person not involved in the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The first group every 28 days will receive one daily soft capsule of clove oil and one placebo tablet of COCs for 21 days and 7 days without using it for three cycles and the second group will receive every 28 days, one daily soft placebo capsule of clove oil and one tablet of COCs for 21 days and 7 days without taking it for three cycles. Original drugs will be identical in shape, color, and weight to their placebo counterparts. Participants, the principal investigator, health care personnel, those assessing the outcome and the safety and data monitoring committee, and those preparing the draft of the article will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Third floor, No 2-central building, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.118

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
The serum levels of dehidroepyandrosteron(DHEA) and total testosterone
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
By the ELISA method using the relevant kits

2

Description
Hirsutism score
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Using the Ferriman–Gallwey scoring system

Secondary outcomes

1

Description
The normalization of menstrual cycles
Timepoint
At the beginning of the study and in each 28-day cycle for 3 cycles during the intervention
Method of measurement
Using the menstrual disorders questionnaire

2

Description
The serum levels of fasting Blood glucose and insulin
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
By spectrophotometry and ELISA method

3

Description
The serum levels of gonadotropins (FSH and LH)
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
By ELISA method using the relevant kits

4

Description
Anthropometric indices (waist circumference, hip circumference, body bass index)
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Using anthropometric tools

5

Description
Quality of life score
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Using the health-related quality of life questionnaire of women with polycystic syndrome made by Cronin et al

Intervention groups

1

Description
Intervention group: Receiving 28 soft capsules of clove oil (containing Eugenol) one daily after lunch, along with 21 placebo LD tablets containing an ineffective substance (exactly the same as LD tablets) one daily after dinner and the following seven days without medication for 3 cycles which will be prepared and packaged by the pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group: Participants in the control group will receive 21 tablets of LD (containing 30 micrograms of ethinyl estradiol and 150 micrograms of levonorgestrel) once daily after dinner and for the next seven days without medication, along with 28 placebo soft capsules containing an inactive substance (precisely the same as clove oil capsules) one daily after lunch for use in a 28-day cycle, which is packaged and numbered and will be prepared by the pharmaceutical company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics of Tabriz University of Medical Sciences
Full name of responsible person
Azizeh Farshbaf-Khalili
Street address
Nutrition Research Center, Tabriz University of Medical Sciences; Attar Neishabouri avenue, Golgasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Fax
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Email
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Azizeh Farshbaf-Khalili
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data on the main outcome will be published

When the data will become available and for how long
Six months after printing the results

To whom data/document is available
Researchers at institutions have access to data

Under which criteria data/document could be used
In order to help scientific progress in the field of research

From where data/document is obtainable
farshbafa@tbzmed.ac.ir

What processes are involved for a request to access data/document
Scientific approval of the applicant by Tabriz University of Medical Sciences

Comments