Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Curcumin on Metabolic Indicators in Women with Polycystic Ovarian Syndrome: A Randomized Controlled Clinical Trial

Protocol summary

Study aim
Comparison of mean serum levels of metabolic factors (fasting insulin, fasting blood glucose, LDL, HDL, and cholesterol) between two groups of Curcumin and placebo, three months after intervention.

Design
Clinical trial, with control group, with parallel groups, triple blind, randomized

Settings and conduct
This triple blind randomized controlled clinical trial will be conducted in Tabriz. Participants will be divided into two groups of intervention and control with a randomized blocking method with an assignment ratio of 1:1. To conceal the allocation, the same black, opaque, and identical pockets will be used, in which the Curcumin capsule or placebo capsule will be put based on the allocation sequence. Preparation of the glass will be carried out by a person who is not involved in sampling and collecting data and analyzing them.The drug and the placebo will be the same in appearance (shape, color and odor), and the packaging of drugs will be done by someone who is not involved in the research

Participants/Inclusion and exclusion criteria
The participants will be women with polycystic ovary syndrome without metabolic diseases and not taking of hormonal treatment.

Intervention groups
The Intervention group will receive oral capsules of curcumin twice a day at a dose of 500 milligrams for 12 weeks. The control group will receive placebo capsules twice a day for 12 weeks

Main outcome variables
The main outcomes will be assessment of serum levels of metabolic factors (fasting insulin, fasting blood glucose, LDL, HDL, and cholesterol) in two groups of curcumin and placebo three months after intervention.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120718010324N51**
Registration date: **2019-11-30, 1398/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-30, 1398/09/09**
Update count: **0**

Registration date
2019-11-30, 1398/09/09

Registrant information
Name
Mojgan Mirghafourvand
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-11-20, 1398/08/29
Expected recruitment end date
2020-04-20, 1399/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Curcumin on Metabolic Indicators in Women with Polycystic Ovarian Syndrome: A Randomized Controlled Clinical Trial

Public title
The effect of curcumin on metabolic indicators in women with polycystic ovarian syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Having sufficient literacy to complete the questionnaire or the presence of a literate person in the family Having polycystic ovarian syndrome BMI Between 25 and 40

Exclusion criteria:
Having other androgenic disorders, such as adrenal hyperplasia or a androgen secreting tumors Having thyroid gland diseases having Cushing's syndrome Taking hormonal contraceptives currently or using hormonal therapy Pregnancy or breastfeeding Previous surgery on one or both ovaries Smoking and drinking alcohol

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

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned into two groups of intervention and control with a block randomization method with an assignment ratio of 1:1. To conceal the allocation, the identical opaque, and numbered sequentially pockets will be used, in which the curcumin capsule or placebo capsule will be put into them. Preparation of pockets will be done by a person not involved in the sampling, data collection and analysis .

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants, researcher and data analyst in this study. The drug and the placebo will be same in appearance (shape, color and odor), and the packaging of drugs will be done by someone who is not involved in the research

Placebo
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
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2019-04-10, 1398/01/21

Ethics committee reference number
IR.TBZMED.REC.1398.017

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Serum levels of metabolic factors (fasting insulin, fasting blood glucose, LDL, HDL, and cholesterol)

Timepoint
Before and 12 weeks after intervention with drug/placebo

Method of measurement
Blood test

Secondary outcomes

1

Description
Hirsutism Score

Timepoint
Before and 12 weeks after intervention with drug/placebo

Method of measurement
Ferriman–Gallwey criteria

2

Description
Anthropometric indices (waist circumference, hip circumference and body mass index)
Timepoint
Before and 12 weeks after intervention with drug/placebo
Method of measurement
Measuring with centimeter and scale

3

Description
Menstrual status
Timepoint
Before and 12 weeks after intervention with drug/placebo
Method of measurement
Menstrual characteristics questionnaire

Intervention groups

1

Description
The intervention group receives two oral capsules of curcumin at a dose of 500 mg for 12 weeks.
Category
Treatment - Drugs

2

Description
The control group received two oral capsules daily from 500 mg for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Nilufar Ghanbarzade Gashti
Street address
Alzahra hospital, Artesh street, Tabriz
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5138665793
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2

Recruitment center
Name of recruitment center
Emam Reza hospital
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3

Recruitment center
Name of recruitment center
Talegani hospital
Full name of responsible person
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4

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

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Samiei

Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

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mirghafourvandm@tbzmed.ac.ir

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
Nilufar Ggahnbarzade Gashti

Position
MSc student of conseling in Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Faculty of Nursing & Midwifery, South Shariati street

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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
PhD of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
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Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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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
Data of participants are privacy.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of clinical study will be published as article.
When the data will become available and for how long
Immediately after publishing the results.
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific using with citation to article.
From where data/document is obtainable
Email: mirghafourvandm@tbzmed.ac.ir
What processes are involved for a request to access data/document
Up to one week after communication by email
Comments