Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effectiveness of Metformin and Curcumin in laboratory criteria in patients with polycystic ovary syndrome

Protocol summary

Study aim

Determining and comparing the effect of metformin and curcumin in pcos patients in terms of anthropometric criteria,blood suger indexes,lipid indexes and hormonal indexes

Design

A double blind ,Randomized clinical trial study with a control group with a sample size of 200 patient.The site WWW.Sealedenvelop.com wase used for block randomization.

Settings and conduct

This study will be conducted in Imam Ali Zahedan Hospital 200 patients with polycystic ovary syndrome were randomly assigned to 4 groups. The first group received 500 mg metformin tablets three times a day for three months, the second group received 80 mg curcumin tablets three times a day for three months. The third group will receive metformin 500 mg tablets together with curcumin 80 mg three times a day for 3 months and the fourth group will receive a placebo drug for three months. The patients and the drug distributor and the analyzer are not aware of the content.

Participants/Inclusion and exclusion criteria

Patients with pcos syndrom which is approved based on Rotterdam criteria provided that dont have hepatic disease,renal disease,thyroid disease,heart disease,other endocrine disorder or sever glucose intolerance

Intervention groups

In this study we have 4 groups Metformin receiving group Curcumin receiving group Metformin and curcumin receiving group placebo receiving group

Main outcome variables

In this study, anthropometric indices and blood sugar indices such as FBS, HOMA-IR and fasting insulin and lipid indices such as TG, LDL, HDLO, total cholesterol and hormonal indices such as FSH, LH and Testosterone will be evaluated and compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221117056528N1**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-29, 1401/09/08**
Update count: **0**

Registration date

2022-11-29, 1401/09/08

Registrant information

Name

Fatemeh Feghhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5253 9916

Email address

hfeghhi93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-26, 1401/09/05

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Metformin and Curcumin in laboratory criteria in patients with polycystic ovary syndrome

Public title
Evaluation of the effectiveness of Metformin and Curcumin in pcos
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with polycystic ovarian syndrom based on the diagnostic criteria of rotterdam including ultrasound examination and symptoms of hyperandrogenism and menstural disorders and ruling out other endocrine disorderssuch as hyperprolactinemia,increase in the thickness of the outer layer of the ovary,cushing syndrom,acromegaly,androgen producing tumors and CAH
Exclusion criteria:
Cardiovascular disease Hepatic disease Renal disease Thyroid disease Sever glucose intolerance User of vitamine and mineral supplementary User of weight reducer drugs
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method In order to hide the random allocation process,random 10-digit codes are written on 200 paper labels whitout a specific order and frame,which is the identification number of the relevant and only the project methodologist is aware of the relevent code.The labels will be struck on the medicine packages in the order of the randomization list.When the doctor declares the eligibility of a patient,the methodologist will provide the pakage treatment plan to him.The evaluator is unaware of the type of traetment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drugs and the placebo will be setting in simillary boxes whitout any name or symptom,and it is provided to the participant by jarh's colleague.The patients and the evaluating researcher are unaware of the type of treatment.In order the analyze the data,a statistician who is not aware of the performed processes will be used.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی زاهدان
Street address
Dr. Hasabi Square, Zahedan Medical Sciences Campus
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2022-10-25, 1401/08/03
Ethics committee reference number
IR.ZAUMS.REC.1401.286

Health conditions studied

1

Description of health condition studied
Polycystic Ovarian Syndrom
ICD-10 code
IV
ICD-10 code description
Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description
Lipid profile level
Timepoint
First and three months after the study
Method of measurement
with laboratory sampling in mg/dL

2

Description
Hormone profile levels such as testosterone and luteinizing hormone and Follicle-stimulating Hormone
Timepoint
First and three months after the study
Method of measurement
with laboratory sampling in IU/l

3

Description
Fasting blood sugar and insulin levels and HOMA-IR
Timepoint
First and three months after the study
Method of measurement
with laboratory sampling in mg/dL

4

Description
Average anthropometric indices such as waist circumference and hip circumference and body mass index
Timepoint
First and three months after the study
Method of measurement
By measuring weight in kilograms and height in centimeters

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: 50 patients with polycystic ovary syndrome who were given metformin tablets 500 mg every 8 hours from Dineh Iran for three months.
Category
Treatment - Drugs

2

Description
Intervention group: The second intervention group: 50 patients with polycystic ovary syndrome who were given 80 mg curcumin tablets every 8 hours from Dineh Iran for three months.
Category
Treatment - Drugs

3

Description
Intervention group: The third intervention group: 50 patients with polycystic ovary syndrome who are given 80 mg curcumin tablets every 8 hours and 500 mg metformin tablets from Iran's Dineh company for three months.
Category
Treatment - Drugs

4

Description
Control group: 50 patients with polycystic ovary syndrome who are given a placebo for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Zahedan Hospital
Full name of responsible person
Fatemeh Feghhi
Street address
Persian Gulf Highway, in front of Imam Khomeini Mosque, Ali Ibn Abi Talib Hospital (AS).
City
Zahedan
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Sistan-va-Balouchestan
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98167 43111
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hfeghhi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Shahraki
Street address
Dr. Hasabi Square, Zahedan University of Medical Sciences
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Web page address
https://zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Fatemeh Feghhi
Position
Obstetrics and Gynecology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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
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
Title and more details about the data/document
It is possible to publish all data anonymously, including laboratory criteria before and after the clinical trial period and changes in body mass and basic criteria such as age and marital status of people.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Use for comparison with other researches in other

centers

From where data/document is obtainable

Dr Fatemeh Feghhi

What processes are involved for a request to access data/document

Having permission to do research work from a reputable center

Comments