

# 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 sugar 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 was 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 syndrome which is approved based on Rotterdam criteria provided that don't have hepatic disease, renal disease, thyroid disease, heart disease, other endocrine disorder or severe 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, HDL, 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 Fegghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5253 9916

##### Email address

hfegghi93@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 menstrual disorders and ruling out other endocrine disorders such 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 relevant 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 package treatment plan to him. The evaluator is unaware of the type of treatment.

#### 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 to 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 Fegghi

##### **Street address**

Persian Gulf Highway, in front of Imam Khomeini Mosque, Ali Ibn Abi Talib Hospital (AS).

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

98167 43111

##### **Phone**

+98 54 3329 5564

##### **Email**

hfegghi@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

##### **City**

zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816743463

##### **Phone**

+98 54 3337 2151

##### **Email**

hfegghi93@gmail.com

##### **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 Fegghi

**Position**

Obstetrics and Gynecology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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054333721514

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Fegghi

**Position**

Obstetrics and Gynecology Resident

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**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Fegghi

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054333721514

**Email**

hfegghi93@gmail.com

**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 Fegghi

**What processes are involved for a request to access**

**data/document**

Having permission to do research work from a reputable center

**Comments**