

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Metformin and pioglitazone in women with polycystic ovary syndrome

Protocol summary

Summary

This study will be a randomized clinical trial to compare the effectiveness of metformin and pioglitazone in treatment of women with polycystic ovary syndrome (PCO). Inclusion criteria: age between 18 to 40 years old; diagnosed PCOS by AES (Androgen excess society 2006) criteria include: 1. Oligo or anovulation 2. Clinical or biochemical hyperandrogenism and rejection any other reason cause to hyperandrogenism. Exclusion criteria: pregnancy and lactation; impaired liver and renal function tests; thyroid disorder; hyperprolactinemia; adrenal disorders; patient on estrogen and progesterone pills; the presence of type 1 and type 2 diabetes mellitus; late-onset congenital adrenal hyperplasia, and Cushing's syndrome; none of the women had been taking clomiphene citrate, oral contraceptives, antiandrogens, insulin, minoxidil, phenytoin, cyclosporine, or drugs to control their appetite, lipid profile, during the previous 3 months and any severe systemic disease. Seventy five women with PCOS aged 18-40 years old will be randomly allocated to one of the three treatment groups. Metformin group (25) will treat with metformin monotherapy (1500mg daily) ; metformin plus pioglitazone group (25) will treat with metformin(1500mg daily) plus pioglitazone(30mg daily) and pioglitazone group(25) will treat with pioglitazone monotherapy(30mg daily) for 3 months. Treatment will be discontinued once pregnancy will diagnose. All patients undergo clinical and biochemical evaluation and analyses involving the pre- and post-intervention fasting blood sugar (FBS), lipid profiles, body mass index (BMI), serum insulin, the homeostatic model assessment of insulin resistance (HOMA-IR), triglyceride, lower density cholesterol, high density cholesterol and DHEAS (dehydroepiandrosterone sulphate) LH/FSH, Total Testosterone, 17-OHP, (17hydroxyprogesterone) waist to hip ratio in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403101836N7**

Registration date: **2014-04-15, 1393/01/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-15, 1393/01/26

Registrant information

Name

Seyed Mojtaba Sohrevardi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5001

Email address

smsohrevardi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-04-09, 1393/01/20

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Metformin and pioglitazone in women with polycystic ovary syndrome

Public title

Evaluation of effectiveness of Metformin and pioglitazone in women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 40 years old; diagnosed PCOS by AES (Androgen excess society 2006) criteria include: 1. Oligo or anovulation 2. Clinical or biochemical hyperandrogenism and rejection any other reason cause to hyperandrogenism. Exclusion criteria: pregnancy and lactation; impaired liver and renal function tests; thyroid disorder; hyperprolactinemia; adrenal disorders; patient on estrogen and progesterone pills; the presence of type 1 and type 2 diabetes mellitus; late-onset congenital adrenal hyperplasia, and Cushing's syndrome; none of the women had been taking clomiphene citrate, oral contraceptives, antiandrogens, insulin, minoxidil, phenytoin, cyclosporine, or drugs to control their appetite, lipid profile, during the previous 3 months and any severe systemic disease.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Sadoughi University of Medical Sciences

Street address

Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences- Shohadaye Gomonam boulevard- Professor Hesabi boulevard- Yazd

City

Yazd

Postal code**Approval date**

2014-03-09, 1392/12/18

Ethics committee reference number

248671 /17/1/پ

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 Insulin level

Timepoint

before intervention and after intervention(after three month)

Method of measurement

mili IU per liter

2**Description**

low density lipoprotein

Timepoint

before intervention and after intervention(after three month)

Method of measurement

mili gram per deciliter

3**Description**

high density lipoprotein

Timepoint

before intervention and after intervention(after three month)

Method of measurement

mili gram per deciliter

4**Description**

triglyceride

Timepoint

before intervention and after intervention(after three month)

Method of measurement

miliigram per deciliter

5

Description

fast blood sugar

Timepoint

before intervention and after intervention (after three month)

Method of measurement

milligram per deciliter

6

Description

dehydroepiandrosterone sulphate

Timepoint

before intervention and after intervention(after three month)

Method of measurement

milligram per liter

7

Description

17hydroxyprogesterone

Timepoint

before intervention and after intervention(after three month)

Method of measurement

microgram per liter

8

Description

Total Testosterone

Timepoint

before intervention and after intervention(after three month)

Method of measurement

microgram per liter

9

Description

LH/FSH ratio

Timepoint

before intervention and after intervention(after three month)

Method of measurement

IU per liter

10

Description

Cholesterol

Timepoint

before intervention and after intervention(after three month)

Method of measurement

milligram per deciliter

Secondary outcomes

1

Description

waist to hip ratio

Timepoint

before intervention and after intervention after three month

Method of measurement

meter

2

Description

Body Mass Index

Timepoint

before intervention and after intervention after three month

Method of measurement

kilogram per square meter

3

Description

side effect of drugs

Timepoint

after intervention (after three month)

Method of measurement

descriptive

4

Description

Homeostatic Model Assessment-Insulin Resistance)
HOMA -IR)

Timepoint

before intervention and after intervention(after three month)

Method of measurement

milli IU per deciliter /milli gram per deciliter

Intervention groups

1

Description

group number 1 (25 patient) metformin 500 mg three times a day (first week 500 mg daily then second week 500 mg two times a day and third week 500 mg three times a day and continuous with 500 mg three times a day for three month)

Category

Treatment - Drugs

2

Description

group number 2 (25 patient) tab pioglitazone 30 mg daily for three month

Category

Treatment - Drugs

3

Description

group number3 (25 patient) tab metformin 500 mg three times a day (first week 500 mg daily then second week 500 mg two times a day and third week 500 mg three times a day and continuous with 500 mg three times a day for three month) and tab pioglitazone 30 mg daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital-khatamol anbiya clinic

Full name of responsible person

Dr seyed mojtaba sohrevardi

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Fatemeh Ezoddini Ardakani

Street address

Research Department, Building No 2, Yazd Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

YYazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Seyed Mojtaba Sohrevardi

Position

PhD of clinical pharmacy/ research assistant of yazd faculty of pharmacy

Other areas of specialty/work

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty