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 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 soiciety2006) criteria include: 1. Oligo or anovulation 2. Clinical or biochemical hyperandrogenism and rejection any other reasen 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 mono-therapy (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 mono –therapy(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, (17hydroxyprogestrone) 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)
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+98 34 1320 5001
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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 soiciety2006) criteria include: 1. Oligo or anovulation 2. Clinical or biochemical hyperandrogenism and rejection any other reasen 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 Gomnam 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
mililgram per deciliter

5

Description
fast blood suger
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
17hydroxyprogestrone
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 dugs
Timepoint
afer 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
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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