Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of metformin and pioglitazone in polycystic ovarian syndrome

Protocol summary

Summary

The objective of this study is to compare the endocrine and metabolic effects of Metformin versus Pioglitazone in women with polycystic ovarian syndrome and menstrual disorder. We randomized 56 women aged 20-49 years old with polycystic ovary syndrome and menstural disorder either to receive Metformin, 500 mg, three times daily or Pioglitazone, 30 mg daily, for 3 months. Metabolic (F.B.S, Insulin, TG, cholesterol, LDL, HDL) and endocrine parameters (Testosterone, DHEAS) were evaluated before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008094179N3**
Registration date: **2010-09-04, 1389/06/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-09-04, 1389/06/13

Registrant information

Name

Karoon Shahebrahimi

Name of organization / entity

Kermanshah Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

k-shahebrahimi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2010-07-10, 1389/04/19

Expected recruitment end date

2011-03-18, 1389/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of metformin and pioglitazone in polycystic ovarian syndrome

Public title

Effects of metformin and pioglitazone in polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: High TSH with FT4 in normal range
Exclusion criteria: receiving Levothyroxine, glucocorticoids, aspirin, amiodaron, lipid lowering agents, OCP, dopamine antagonist eg. metoclopramide and domperidone in recent 6 months, diabetic patients, pregnant women, women in menopause ages, patients older than 60 years

Age

From **20 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences and Health Servises
Street address
Shahid Beheshti boulevard, Kermanshah
City
kermanshah
Postal code
Approval date
2010-06-15, 1389/03/25
Ethics committee reference number
205/420/7/پ

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Endocrine nutritional and metabolic diseases

Primary outcomes

1

Description
Blood pressure
Timepoint
3 months
Method of measurement
Barometers

2

Description
Fasting sugar serum level
Timepoint
3 months
Method of measurement
mg/dl

3

Description
Fasting Insulin serum level
Timepoint
3 months
Method of measurement
Uiu/ml

4

Description
Testostrone serum level
Timepoint
3 months
Method of measurement
ngr/dl

5

Description
DHEADS serum level
Timepoint
3 months
Method of measurement
ngr/dl

Secondary outcomes

1

Description
Cholesterol serum level
Timepoint
3 months
Method of measurement
mg/dl

2

Description
Triglyceride serum level
Timepoint
3 months
Method of measurement
mg/dl

3

Description
LDL serum level
Timepoint
3 months
Method of measurement
mg/dl

4

Description
HDL serum level
Timepoint

3 months

Method of measurement

mg/dl

Intervention groups

1

Description

Metformin 500 mg three times dialy, orally for 3 month.

Category

Treatment - Drugs

2

Description

Pioglitazone 30 mg dialy, orally for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dr Nasrin Bazgir

Street address

City

kermanshah

2

Recruitment center

Name of recruitment center

Shafa clinic

Full name of responsible person

Dr Nasrin Jalilian

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Kermanshah University of Medical Science

Full name of responsible person

Dr Farid Najafi

Street address

Shahid Beheshti boulevard, Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research, Kermanshah University of Medical Science

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Karoon Shahebrahimi

Position

Fellowship of adult's endocrine and metabolic disease

Other areas of specialty/work

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Person responsible for updating data

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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