

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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 menstrual 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

+98 83 1427 6303

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 Services

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

Testosterone 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 daily, orally for 3 months.

Category

Treatment - Drugs

2

Description

Pioglitazone 30 mg daily, 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 scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Nasrin Bazgir

Position

Internal Medicine Resident

Other areas of specialty/work**Street address**

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Web page address

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