

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of metformin versus acarbose and metformin in clinical presentation and endocrinology profiles in polycystic ovarian syndrome patients

Protocol summary

Summary

This study is a randomized double-blind clinical trial and aim is to investigate the effect of metformin versus metformin and acarbose on the clinical manifestation and endocrine/metabolic change in polycystic ovarian syndrome. inclusion criteria: age 20-45 years; women with pcos diagnosed by the rotterdam consensus criteria Exclusion criteria: patient with systemic disease or endocrine disease; androgen secreting tumor; smokers; receiving any drug for pcos. we randomized 68 women with polycystic ovarian syndrome to receive either tab metformin 500 mg and tab acarbose 100mg one time daily or tab metformin 500mg three times daily and tab placebo one time daily for 4 months. metabolic (f.b.s, insulin, triglycerid, cholestrol, LDL, HDL) and endocrine parameters (testosterone, DHEAS) and clinical manifestation (hirsutism, blood pressure) were evaluated before and after the intervention and data compared statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082214438N1**

Registration date: **2013-10-15, 1392/07/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-15, 1392/07/23

Registrant information

Name

Maryam Karimian

Name of organization / entity

Kermanshah University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Kermanshah University Of Medical Sciences, Research Vice_Presidency

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of metformin versus acarbose and metformin in clinical presentation and endocrinology profiles in polycystic ovarian syndrome patients

Public title

Comparison of the effect of metformin versus acarbose and metformin in treatment polycystic ovarian syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20-45 years; women with pcos diagnosed by the rotterdam consensus criteria (presence 2 of the following 3 conditions: a) oligomenorrhea

/amenorrhea b)clinical or biochemical evidence of hyperandrogenism c)polycystic ovaries on sonography)
Exclusion criteria: patient with systemic disease such as cushing's syndrome; hyper or hypothyroidism; androgen secreting tumor; smokers; any systemic disease (liver ,renal,cardiovascular,diabet mellitus) ; receiving any drug for pcos such as aldacton,dian and clomiphen.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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 Science and Health Servises

Street address

Shahid Beheshti Street, Kermanshah

City

Kermanshah

Postal code

Approval date

2012-12-09, 1391/09/19

Ethics committee reference number

41192

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

sclerocystic ovary syndrome

Primary outcomes

1

Description

Hirsutism

Timepoint

Before intervention - Four months after intervention

Method of measurement

Using Feriedman and Galway Scale

2

Description

Testostrone serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Serological test with Electr Komolomysans method

3

Description

De Hydro Epi Andrestandion serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Serological test with Electr Komolomysans method

4

Description

Fasting insulin serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Elysa asses

5

Description

Fasting sugar serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Enzyme

6

Description

Blood pressure

Timepoint

Before intervention - Four months after intervention

Method of measurement

Barometers

Secondary outcomes

1

Description

Triglycerid serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Serological test with Electro Komolynsans method

2

Description

Cholestrol serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Serological test with Electro Komolynsans method

3

Description

LDL serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Serological test with Electro Komolynsans method

4

Description

HDL serum level

Timepoint

Before intervention - Four months after intervention

Method of measurement

Serological test with Electro Komolynsans method

Intervention groups

1

Description

Tab metformin 500mg three times daily,orally and tab acarbose 100mg one time daily,orally for 4months

Category

Treatment - Drugs

2

Description

Tab metformin 500mg three times daily,orally and tab placebo one time daily/orally for 4months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Maryam Karimian, MD

Street address

Sorkhelije, Kermanshah

City

Kermanshah

2

Recruitment center

Name of recruitment center

Shafa Clinic

Full name of responsible person

Nasrin Jalilian, MD

Street address

Shahrdari Street, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University Of Medical Svience, Research Vice-Presidency

Full name of responsible person

Dr. Farid Najafi

Street address

Shahid Beheshti Street, Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University Of Medical Svience, Research Vice-Presidency

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 Science

Full name of responsible person

Maryam Karimian, MD

Position

Internal Medicine Resident

Other areas of specialty/work

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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