Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 rececive 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.metabolic9f.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 statitcaly.

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

Iran (Islamic Republic of)

Phone

+98 83 1427 6302

Email address

maryam.karimian@kums.ac.ir

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 Komolomynsans method

3

Description
De Hydro Epi Andrestandion serum level

Timepoint
Before intervention - Four months after intervention

Method of measurement
Serological test with Electr Komolomynsans 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
Street address
Shahid Beheshti Street, Kermanshah
City
Kermanshah
Postal code
Phone

+98 83 1427 6303
Fax
+98 83 1427 6343
Email
maryam.karimian@kums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University Of Medical Science
Full name of responsible person
Karoon Shahebrahimi, MD
Position
Endocrinologist
Other areas of specialty/work
Street address
Emam Reza Hospital, Kermanshah
City
Kermanshah
Postal code
Phone
+98 83 1427 6309
Fax
+98 83 1427 6343
Email
dr_shahebrahimi@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Shahid Beheshti Street, Kermanshah
City
Kermanshah
Postal code
Phone
+98 83 1427 6303
Fax
+98 83 1427 6343
Email
maryam.karimian@kums.ac.ir
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