

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

A clinical trial to compare the effects of acarbose and metformin use on ovulation induction success in women with polycystic ovary syndrome

Protocol summary

2014-11-05, 1393/08/14

Summary

The aim of this randomized single blind clinical trial study is to investigate the effect of acarbose and metformin use on ovulation induction success in women with polycystic ovary syndrome. Inclusion criteria: age 20-40 years, women with polycystic ovary syndrome diagnosed by the rotterdam consensus criteria. Exclusion criteria: Smoking, Cushing's syndrome, thyroid function disorders, androgen secreting tumors, patients with liver disease, kidney disease, heart disease, diabetes, and use of other drugs for polycystic ovary syndrome. A total of 60 women with polycystic ovarian syndrome were selected and randomly divided in two control and intervention groups using block method of 4. Intervention group receive acarbose 100 mg/day for 3 months. This method that in the first week they receive 1 tablet, second week two tablets and third week three tablets per day. Control group receive metformin 500 mg/day for 3 months. This method that in the first week they receive 1 tablet, second week two tablets and third week three tablets per day. All patients underwent laboratory examination before intervention including metabolic parameters (fasting sugar, fasting insulin, triglycerides and cholesterol) and clinical performance (hirsutism and hypertension). At the end of 3 months for the above they shall be examined and compared.

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-01-05, 1393/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092912789N7**

Registration date: **2014-11-05, 1393/08/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

A clinical trial to compare the effects of acarbose and metformin use on ovulation induction success in women with polycystic ovary syndrome

Public title

Comparison of the effects of acarbose and metformin on ovulation induction success

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20-40 years, women with

polycystic ovary syndrome diagnosed by the rotterdam consensus criteria. Exclusion criteria: Smoking, Cushing's syndrome, thyroid function disorders, androgen secreting tumors, patients with liver disease, kidney disease, heart disease, diabetes, and use of other drugs for polycystic ovary syndrome.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Researcher is not aware of patient grouping. Patients were followed by resident of gynecology during the study period.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City

Sanandaj

Postal code**Approval date**

2014-09-29, 1393/07/07

Ethics committee reference number

14/26288

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**

Hirsutism

Timepoint

Before intervention -Three months after intervention

Method of measurement

Using Feriedman and Galway Scale

2**Description**

Fasting insulin serum level

Timepoint

Before intervention -Three months after intervention

Method of measurement

Elisa assays

3**Description**

Fasting sugar serum level

Timepoint

Before intervention -Three months after intervention

Method of measurement

Enzyme

4**Description**

Blood pressure

Timepoint

Before intervention -Three months after intervention

Method of measurement

Barometers

Secondary outcomes**1****Description**

Triglyceride serum level

Timepoint

Before intervention -Three months after intervention

Method of measurement

Serological test with Electro Komolynsans method

2**Description**

Cholestrol serum level

Timepoint

Before intervention -Three months after intervention

Method of measurement

Serological test with Electro Komolynsans method

3

Description

LDL serum level

Timepoint

Before intervention -Three months after intervention

Method of measurement

Serological test with Electro Komolynsans method

4

Description

HDL serum level

Timepoint

Before intervention -Three months after intervention

Method of measurement

Serological test with Electro Komolynsans method

Intervention groups

1

Description

Intervention group receive acarbose 100 mg/day for 3 months. This method that in the first week they receive 1 tablet, second week two tablets and third week three tablets per day.

Category

Treatment - Drugs

2

Description

Control group receive metformin 500 mg/day for 3 months. This method that in the first week they receive 1 tablet, second week two tablets and third week three tablets per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Somaye Mohammadpour

Street address

Besat Hospital, Keshavarz St., Mardokh Cross Road, Sanandaj, Iran

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kurdistan University of

Medical Sciences

Full name of responsible person

Fardin Gharibi

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City

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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, Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Somaye Mohammadpour

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Masomeh Rezaei

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Full name of responsible person

Somaye Mohammadpour

Position

Resident of Obstetrics and Gynecology

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

Besat Hospital, Keshavarz St., Mardokh Cross Road,

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