

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigation and comparison of the effect of metformin and rosiglitazone alone and in combination on ovarian and endometrium among polycystic ovarian syndrome patients

Protocol summary

Summary

Metformin and rosiglitazone both are used to treat polycystic ovary syndrome. In this study we aimed to compare the effects of these two drugs to treat this syndrome. To do so we are going to select 44 patients who suffer from polycystic ovary syndrome that refer to Al-Zahra or Shahid Beheshti hospitals and meet inclusion criteria. Then we randomly assign them into two groups. All patients will be followed without any treatment for six weeks, and then each patient will use metformin or rosiglitazone alone for 12 weeks. After this phase, all patients will use the combination of two drugs. All patients will undergo sonography, endometrial biopsy and laboratory tests before drug use, 12 weeks after beginning the drug and 12 weeks after using combination of two drugs. Some inclusion criteria include: age between 18-40 years, not consumption of drugs which change sexual hormones metabolism for at least 1 month before trial, not using contraceptive pills for at least 3 months before the trial. In the case of pregnancy, anemia, type 2 diabetics, hyperprolactinemia and any disorder in liver or kidney functions patient will be excluded from the study. The size of ovary, endometrium density, blood sugar, body mass index and hirsutism will be determined for all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605257513N12**

Registration date: **2016-07-22, 1395/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-22, 1395/05/01

Registrant information

Name

Hatav Ghasemi Tehrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 113 4081

Email address

tehrani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison of the effect of metformin and rosiglitazone alone and in combination on ovarian and endometrium among polycystic ovarian syndrome patients

Public title

Comparison the effect of Metformin and Rosiglitazone, alone and in combination, to treat polycystic ovary

syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: females between 18-40 years old; euthyroid; non smoker; normal physical condition; not consumption of drugs that change sexual hormones metabolism for at least 1 month before trial; not using contraceptive pills for at least 3 months before the trial. Exclusion criteria: classic 21_hydroxylase deficiency; hyperprolactinemia; androgen producing tumor; pregnancy; impaired liver tests or kidney function disorder; type 2 Diabetes; anemia; thrombocytopenia; explicit hypertension.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features
Since the list of patients is available, 44 patients of these two centers will be selected by simple random sampling method. Then the name of each patient will be separately written on a card, and 22 cards will be chosen randomly. These patients will receive the first intervention and those remaining patients will be assigned into second intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib Av.

City

Isfahan

Postal code

Approval date

2014-04-16, 1393/01/27

Ethics committee reference number

394050

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Ovarian size

Timepoint

At the beginning of the study, after one-drug usage period, after the period of treatment with combination of two drugs

Method of measurement

Trans vaginal sonography

2

Description

Endometrium density

Timepoint

At the beginning of the study, after one-drug usage period, after the period of treatment with combination of two drugs

Method of measurement

Trans vaginal sonography

Secondary outcomes

1

Description

Blood sugar

Timepoint

At the beginning of the study, after one-drug usage period, after the period of treatment with combination of two drugs

Method of measurement

Laboratory tests

2

Description

Hirsutism

Timepoint

At the beginning of the study, after one-drug usage period, after the period of treatment with combination of two drugs

Method of measurement

Ferriman criteria

3

Description

BMI

Timepoint

At the beginning of the study, after one-drug usage period, after the period of treatment with combination of two drugs

Method of measurement

Division of weight to squared height

Intervention groups

1

Description

Metformin intervention group: Patients will be followed without any drug for the first 6 weeks. Then they will receive metformin alone for 12 weeks. After that they will receive the combination of metformin and rosiglitazone for 12 weeks.

Category

Treatment - Drugs

2

Description

Rosiglitazone intervention group: Patients will be followed without any drug for the first 6 weeks. Then they will receive rosiglitazone alone for 12 weeks. After that they will receive the combination of metformin and rosiglitazone for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic of Al-Zahra hospital

Full name of responsible person

Maryam Hoseini Roozbahani

Street address

Al-Zahra University Hospital, Sofe Blvd, Keshvari Highway

City

Isfahan

2

Recruitment center

Name of recruitment center

Gynecology clinic of Shahid Beheshti hospital

Full name of responsible person

Maryam Hoseini Roozbahani

Street address

Shahid Beheshti hospital, Beside Felezi bridge, Matahari Av.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research of Isfahan University of Medical Sciences

Full name of responsible person

Mrs.Daneshvar

Street address

Vice chancellor of research, Isfahan University of Medical Sciences, Hezar jarib Av.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research of Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Ferdos Mebrabian

Position

Associate professor of Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Maryam Hoseini Roozbahani

Position

Resident of Gynecology

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