

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of Metformin, Flutamide + oral contraceptives and Simvastatin Effects on Metabolic complications of Polycystic Ovary Syndrome

Protocol summary

Summary

The purpose of this study is to determine and comparison of three treatments, Metformin, Flutamide incombination with oral contraceptives and Simvastatin, effects on metabolic complications of polycystic ovary syndrome. This study is a single blind, multicenter, clinical trial. The physician who is responsible for physical examination and clinical assessments will be blind about the therapeutic intervention of each patient. Subjects will be recruited from polycystic ovary syndrome and metabolic syndrome patients, which refer to midwifery clinic of Al-Zahra and Beheshti hospitals, Isfahan, Iran. Subjects, who will enter to study, are women of at least 18 years old, who are single. They should have no evidence of thyroid dysfunction, Cushing syndrome, hyperprolactinaemia and breast cancer. They also should consent to participate in trial, and normal kidney function, bilirubin level, and serum aminotransferases. After the inclusion, participants who have no desire to continue the study, get married, or faced to drug side effects will be excluded from study. Estimated sample size for the study is 111 subjects. Participants will be randomly assigned into three groups and each group will receive one of the therapeutic interventions. Participants will be undergone the treatment for 6 month. Subsequently, the effect of each therapeutic will be evaluated on insulin resistance, blood pressure, fasting blood sugar, lipid profiles and CRP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405217513N10**

Registration date: **2015-05-15, 1394/02/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-15, 1394/02/25

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

Isfahan University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Metformin, Flutamide + oral contraceptives and Simvastatin Effects on Metabolic complications of Polycystic Ovary Syndrome

Public title

Comparison of Metformin, Flutamide and Simvastatin

Effects on Metabolic complications of Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age ≥ 18 years; being single; having no evidence for thyroid dysfunction, Cushing syndrome, and hyperprolactinaemia; to have normal kidney function, bilirubin level, and serum aminotransferases; none-smoker; not having breast cancer; not using any drug which probably affects the Ovarian function; insulin sensitivity and lipid profile; No contraindication to use drugs. Exclusion criteria: to refuse to continue the study; marriage; emerging side drugs effects or contraindication; not to comply the study protocol.

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences- Hezar jarib Ave. - Isfahan

City

Isfahan

Postal code

Approval date

2012-05-21, 1391/03/01

Ethics committee reference number

394074

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

insulin resistance

Timepoint

baseline and after 6 month

Method of measurement

Homa-IR formula

2

Description

fasting blood sugar

Timepoint

baseline and after 6 month

Method of measurement

mg/dl

3

Description

C-reactive protein

Timepoint

baseline and after 6 month

Method of measurement

mg/liter

4

Description

blood pressure

Timepoint

baseline and after 6 month

Method of measurement

Blood pressure > 130/85 (mmHg)

Secondary outcomes

1

Description

BMI

Timepoint

baseline - after 6 month

Method of measurement

weight (kg)/ height square (m)

2

Description

waist circumference

Timepoint

baseline - after 6 month
Method of measurement
cm

Intervention groups

1

Description
1000mg Meformin per day
Category
Treatment - Drugs

2

Description
62.5mg Flutamid + low dose oral contraceptives (OC)
per day
Category
Treatment - Drugs

3

Description
20mg Simvastatin per day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Street address
City
Isfahan

2

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
research management
Street address
School of Medicine - Isfahan University of Medical
Sciences - Hezar jarib Ave.

City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
School of Medicine
Full name of responsible person
Mahboobe Mohamadkhani
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Resident
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Person responsible for scientific inquiries

Contact
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Department of Obstetrics and Gynecology, School of
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Person responsible for updating data

Contact

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Phone
00

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