

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

Position

Resident

Other areas of specialty/work

Street address

School of Medicine in Isfahan University of Medical
Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Obstetrics and Gynecology, School of
Medicine, Isfahan University of Medical Sciences

Full name of responsible person

Hatav Ghasemi-Tehrani

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical sciences
Full name of responsible person
Mahboobe Mohamakhani
Position
Resident
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Street address
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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