

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of metformin in different phenotypes of poly cystic ovary syndrome according to Rotterdam criteria criteria

Protocol summary

Summary

The purpose of this randomized clinical trial was to determine the effect of metformin on ovulation and pregnancy rate in different phenotypes of PCOD according to Rotterdam criteria. The patients are divided into four phenotypes. This patients randomized to the metformin arm were given the tablets at total dose of 1500 mg per day during two months and then induction ovulation with Letrozole was done. Another group, randomized to the letrozole only arm, were given Letrozole at a dose 5 mg per day on days 2-6. Transvaginal sonography was done to document follicular growth and ovulation, when size of follicle reached 18 mm, HCG were used, then after 24 hours IUI was done. Transvaginal sonography was done 6 weeks after LMP, to determine clinical pregnancy.

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science and Health Service

Expected recruitment start date

2010-07-07, 1389/04/16

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103146063N1**

Registration date: **2011-06-02, 1390/03/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-02, 1390/03/12

Registrant information

Name

Fateme Sarvi

Name of organization / entity

Shariati Hospital, Fertility center

Country

Iran (Islamic Republic of)

Phone

Scientific title

The effect of metformin in different phenotypes of poly cystic ovary syndrome according to Rotterdam criteria criteria

Public title

The effect of metformin in different phenotypes of poly cystic ovary syndrome according to Rotterdam criteria criteria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women were included in the patients attending the outpatient clinic of the Infertility Research Centre of Shariati Hospital. The diagnosis of PCOD was based on the Rotterdam criteria, age between 18 to 35 years, normal thyroid, liver and kidney, normal sperm count according to WHO criteria, taking no metformin in previous 8 weeks, normal hysterosalpingography
Exclusion criteria: mullerian anomaly, abnormal sperm count, thyroid, liver or kidney dysfunction

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **290**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Science and Health
Services

Street address

Ghods St, Keshavarz Blvd

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Postal code**Approval date**

2011-02-24, 1389/12/05

Ethics committee reference number

89/130/1483/3

Health conditions studied**1****Description of health condition studied**

poly cystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

PCOD (poly cystic ovary syndrome)

Primary outcomes**1****Description**

clinical pregnancy rate

Timepoint

three months and half after starting the treatment

Method of measurement

trans vaginal sonography

2**Description**

ovulation rate

Timepoint

two months and half after starting the treatment

Method of measurement

transvaginal sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention: metformin tablet 500 mg TDS from two months before starting ovulation induction, then ovulation induction started on day 2-6 of menstrual cycle with Letrozole 2.5 mg twice per day, when dominant follicle reached 18 mm , human chorionic gonadotropin 10000 IU was injected.

Category

Treatment - Drugs

2**Description**

In control groups: no drug used before starting ovulation induction, then ovulation induction started on day 2-6 of menstrual cycle with Letrozole tablet 2.5 mg twice per day, when dominant follicle reached 18 mm, human chorionic gonadotropin 10000 IU was injected.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shariati Hospital, Infertility Centre

Full name of responsible person

Fatemeh Sarvi

Street address

Amirabad Ave, Gisha Brd

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Tehran University of Medical Science and Health
Service

Full name of responsible person

Fatemeh Sarvi

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Amirabad Ave, Gisha Brd

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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

Tehran University of Medical Science and Health Service

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**

Tehran University of Medical Science and Health
Service, Shariati Hospital

Full name of responsible person

Fatemeh Sarvi

Position

Gynecologist and Fellowship in Infertility

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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