Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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.

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
+98 21 8800 8810
Email address
fsarvi@razi.tums.ac.ir

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

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 to35 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
City
Tehran
Postal code
Approval date
2011-02-24, 1389/12/05
Ethics committee reference number
89/130/1483/ɔ

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
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Science and Health Service
Full name of responsible person
Fatemeh Sarvi
Street address
Amirabad Ave, Gisha Brd
City
Tehran
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
Other areas of specialty/work
Street address
Amirabad Ave, Gisha Brd
City
Tehran
Postal code
Phone
+98 21 8800 8810
Fax
+98 21 8822 0050
Email
fsarvi@razi.tums.ac.ir sarvi.fateme@yahoo.com
Web page address

Person responsible for scientific 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
Other areas of specialty/work
Street address
Amirabad Ave, Gisha Brd
City
Tehran
Postal code
Phone
+98 21 8800 8810
Fax
+98 21 8822 0050
Email
fsarvi@razi.tums.ac.ir sarvi.fateme@yahoo.com
Web page address

Person responsible for updating data

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
Other areas of specialty/work
Street address
Amirabad Ave, Gisha Brd, Shariati Hospital
City
Tehran
Postal code
Phone
+98 21 8800 8810
Fax
+98 21 8822 0050
Email
fsarvi@razi.tums.ac.ir sarvi.fateme@yahoo.com
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