

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Metformin-Letrozole in comparison with Metfomin-Clomiphene citrate in infertile clomiphene resistant polycystic ovary patients undergoing intrauterine insemination

Protocol summary

Summary

Objective: The Present study is designed to compare Metformin-letrozole with Metformin - Clomiphene citrate in clomiphene resistance PCO patients undergoing IUI. Materials and Methods: In this single blind randomized trial, ovarian cycles were studied in 100 clomiphene-resistant PCOS patients with normal liver, kidney and thyroid function. They were randomly allocated to Metformin-Letrozole group (n = 50) and Metformin-Clomiphene citrate group (n = 50). Chemical and clinical pregnancies were assessed after IUI. Abortion rates were determined in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807262604N1**
Registration date: **2011-01-16, 1389/10/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-16, 1389/10/26

Registrant information

Name

Robab Davar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

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Email address

davar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and clinical center for infertility, Shahid Sadoughi university of medical sciences

Expected recruitment start date

2007-04-01, 1386/01/12

Expected recruitment end date

2008-11-21, 1387/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Metformin-Letrozole in comparison with Metfomin-Clomiphene citrate in infertile clomiphene resistant polycystic ovary patients undergoing intrauterine insemination

Public title

Comparison of Clomiphene and Letrozole in association with Metfomin in patients with anovulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: polycystic ovary syndrome, Clomiphene resistant, normal liver function, normal kidney function, normal thyroid function. Exclusion criteria: use of Clomiphene in previous 2 months, use of metformin in previous 2 months.

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

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

Ethics committee of research and clinical center for infertility

Street address

Research and clinical center for infertility, BouAli 2 avenue, Safaieh

City

Yazd

Postal code

8916877391

Approval date

2007-10-08, 1386/07/16

Ethics committee reference number

1581

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

endometrial thickness on day of HCG administration

Timepoint

one time in each cycle

Method of measurement

distance between two layer endometrium measured by

sonography

2

Description

estrogen level on day of HCG administration

Timepoint

one time in each cycle

Method of measurement

measurement of estrogen in serum

3

Description

number of follicles>18mm

Timepoint

every other day from cycle day 12

Method of measurement

by counting of follicles more than18 millimeter in sonography

4

Description

chemical pregnancy

Timepoint

2 weeks after IUI

Method of measurement

by measurement of HCG level in serum

5

Description

clinical prgnancy

Timepoint

one time in each cycle

Method of measurement

observation of gestational sac in sonography

Secondary outcomes

1

Description

abortion rate

Timepoint

one time in each treatment cycle

Method of measurement

observation of expulsion of product of conception from uterous, disappearance of gestational sac in sonography, HCG level in serum dropped or become negative

Intervention groups

1

Description

Metformin 1500mg/day for 6-8 weeks then Metformin + Clomiphene 100mg for 5 days from third day of cycle

Category

Treatment - Drugs

2

Description

Metformin 1500 mg/day for 6-8 weeks then Metformin +
Letrozole 5 mg/day for 5 days from third day of cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and clinical center for infertility, Shahid
Sadoughi university of medical sciences

Full name of responsible person

Robab Davar M.D, obstetrician and gynecologist
(assistant professor)

Street address

Research and clinical center for infertility, Bou-Ali 2,
Safaieh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and clinical center for infertility, Shahid
Sadoughi university of medical sciences

Full name of responsible person

Abbas Aflatounian M.D, obstetrician and gynecologist,
fellowship of infertility (professor)

Street address

Research and clinical center for infertility, Bou-Ali 2,
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Grant name

1290007

Grant code / Reference number

10533

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

Yes

Title of funding source

Research and clinical center for infertility, Shahid
Sadoughi 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

Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences

Full name of responsible person

Robab Davar M.D.

Position

obstetrician and gynecologist (assistant professor)

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

obstetrician and gynecologist (assistant professor)

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