

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparing the treatment outcomes between letrozole and Clomiphene citrate (CC) combined with Gonadotropins in CC resistant Polycystic Ovarian Syndrome (PCOS) patients

Protocol summary

Summary

The aim of this study is to compare the treatment outcome between letrozole and Clomiphene citrate (CC) combined with Gonadotropins in CC resistant Polycystic Ovarian Syndrome (PCOS) patients. A total of 130 patients with PCOS referring to Al-Zahra infertility clinic will be recruited after signing written informed consents. The patients in the first group will receive Clomiphene Citrate, 100mg/day and in the second group letrozole 5mg/day is started from the third day of menstrual cycle to seventh day and gonadotropin F will be used from 7th day at a fixed dosage of 75 IU in both groups. Transvaginal ultrasonography will be performed on tenth day in order to measure endometrial thickness and follicular size and the dosage adjusted in the case of inappropriate follicle size, 10000IU HCG is given intramuscularly when at least one follicle reaches to a size of 18-20 mm and IUI will be applied after 36-40 hours later. E2 will also be measured on the day of HCG injection. The patients with more than three dominant follicles or inadequate response or absence of at least one dominant follicle on twelfth day of the cycle will be excluded. Rate of ovulation, pregnancy rate and treatment failure will be compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106271233N2**
Registration date: **2011-07-30, 1390/05/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-07-30, 1390/05/08

Registrant information

Name

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Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research Guilan University of Medical Sciences

Expected recruitment start date

2011-09-12, 1390/06/21

Expected recruitment end date

2013-09-12, 1392/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the treatment outcomes between letrozole and Clomiphene citrate (CC) combined with Gonadotropins in CC resistant Polycystic Ovarian Syndrome (PCOS) patients

Public title

Comparison of treatment outcomes between letrozole with Gonadotropins in Polycystic Ovarian Syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having PCOS according to Rotterdam criteria and, infertility for one year, age 20-39 years old

Exclusion criteria: tubal obstruction, infertility with male factor, hypersensitivity to Clomiphene Citrate or letrozole, presence of diabetes, thyroid or kidney disease, ovarian drilling, ovarian cyst on day 3 of menstrual cycle

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for Research, Guilan University of Medical Sciences

Street address

Mellat St., Namjoo Ave.

City

Rasht

Postal code

Approval date

2010-12-11, 1389/09/20

Ethics committee reference number

11937

Health conditions studied

1

Description of health condition studied

Disorders of other endocrine glands

ICD-10 code

E28

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Endometrial thickness

Timepoint

Every 2-3 days

Method of measurement

Transvaginal ultrasonography

Secondary outcomes

1

Description

Follicles greater than 16mm

Timepoint

Every 2-3 days

Method of measurement

Transvaginal sonography

2

Description

Clinical pregnancy

Timepoint

14days after IUI

Method of measurement

Ultrasonography two weeks after positive BHCG for finding gestetaional sac

3

Description

Chemical pregnancy

Timepoint

14days after IUI

Method of measurement

bHCG measurment

4

Description

E2 level

Timepoint

Once in a cycle

Method of measurement

On the day of HCG injection by blood sampling

5

Description

Cancellation rate

Timepoint

Every 2-3 days

Method of measurement

Transvaginal sonograhly

6

Description

The number of Gonadotropines used

Timepoint

at the end of the cycle

Method of measurement

Number of Ampoules

Intervention groups

1

Description

Clomiphene citrate is started from day 3 to 7 then Gonal F 75IU/day is used from 7th day of menstrual cycle

Category

Treatment - Drugs

2

Description

Letrozol is started from day 3 to 7 then Gonal F 75IU/day is used from 7th day of menstrual cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research-Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasol Sobhani

Street address

Mellat St., Namjoo Ave. Vice Chancellor for research

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research-Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Dr. Maryam Asgharnia

Position

Associate Professor- Guilan University of Medical Sciences

Other areas of specialty/work

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

B.S Midwife

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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