Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 gonal F will be used from 7th day at a fix 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
Maryam Asgharnia
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 13 1322 5624
Email address
asgharnia@gums.ac.ir

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 sonograhy

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
Giulan 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
Street address
Reproductive Health research center-Alzahra hospital-Namjo street
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
maryamasgharnia@yahoo.comh_fertility@gums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Giulan 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
Street address
Reproductive Health research center-Alzahra hospital-Namjo street
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
maryamasgharnia@yahoo.comh_fertility@gums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person
Seyedeh Fatemeh Dalil Heirati

Position
B.S Midwife

Other areas of specialty/work

Street address
Reproductive Health research center-Alzahra hospital-Namjo street

City
Rasht

Postal code

Phone
+98 13 1322 5624

Fax

Email
fatemehdalil@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