Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

comparison of Letrozole and Clomiphene in combined regimens with gonadotropins in pregnancy rate in pcos patients with clomiphene resistant polycystic ovarian syndrome.

Protocol summary

Summary

The aim of this study was to compare Letrozole and Clomiphene effects, in combination with Gonadotropins, on pregnancy rate in ovulation induction cycles in Clomiphene-resistant patients with polycystic ovarian syndrome. 120 patients with PCOS referred to kashan infertility clinic were enrolled in this randomized clinical trial and were randomly assigned to receive 100mg Clomiphene citrate or 5mg Letrozole daily on days 3 – 7 of menstrual cycle. Patients on both groups received 150IU HMG intramascularly on days 5 – 8 of menstrual cycle, as well. On tenth or eleventh day of menstrual cycle, transvaginal sonography was performed in order to determine endometrial thickness and dominant follicle size and HMG dose was increased, if needed. HCG at a dose of 5000 IU was administered when at least one mature follicle was observed. β-HCG was measured 2 weeks after HCG administration. Number of mature follicles, endometrial thickness, amount of Gonadotropins consumed, and pregnancy rate were compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810132967N1**
Registration date: **2010-02-27, 1388/12/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-02-27, 1388/12/08

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Kashan University of Medical Sciences

Expected recruitment start date

2007-06-22, 1386/04/01

Expected recruitment end date

2009-05-18, 1388/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of Letrozole and Clomiphene in combined regimens with gonadotropins in pregnancy rate in pcos patients with clomiphene resistant polycystic ovarian syndrome.

Public title

comparison of Letrozole and Clomiphene in combined regimens with gonadotropins in pregnancy rate in pcos patients with clomiphene resistant polycystic ovarian syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Clomiphene resistant polycystic ovarian syndrome, age 20-35 years Exclusion criteria: BMI more than 27, presence of hypothyroidism, hyperprolactinemia, or decreased ovarian reserve, male factor infertility, tubal or uterine factor diagnosed by HSG, peritoneal factor (history of previous surgery)
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
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
Kashan University of Medical Sciences
Street address
Vice-chancellor for Research, Ghotbe Ravandi Blvd, Kashan
City
Kashan
Postal code
Approval date
2007-06-09, 1386/03/19
Ethics committee reference number
8755

Health conditions studied

1

Description of health condition studied
Clomiphene resistant polycystic ovarian syndrome
ICD-10 code
N80
ICD-10 code description
Noninflammatory disorders of female genital tract

Primary outcomes

1

Description
Endometrial thickness
Timepoint
Tenth or eleventh day of menstrual cycle
Method of measurement
Transvaginal sonography

2

Description
Ovarian response
Timepoint
Tenth or eleventh of menstrual cycle
Method of measurement
Transvaginal sonography

Secondary outcomes

1

Description
Gonadotropin ampule consuption
Timepoint
Tenth or eleventh of menstrual cycle
Method of measurement
Transvaginal sonography

2

Description
Pregnancy rate
Timepoint
Two weeks after HCG injection
Method of measurement
pregnancy test

Intervention groups

1

Description
Letrozole 5mg (2 tablets) orally from 3-7 days of menstrual cycle in addition to gonadotropine (HMG) ampule 5th to 9th days of menstrual cycle which was continued on tenth or eleventh day of cycle after trasvaginal sonography, if needed
Category
Treatment - Drugs

2

Description
Clomiphene 100mg (2 tablets) from 3-7 days of menstrual cycle in addition to gonadotropine (HMG) ampule 5th to 9th days of menstrual cycle which was continued on tenth or eleventh day of cycle after trasvaginal sonography, if needed
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic
Full name of responsible person
Dr. Fatemeh Foroozanfard
Street address
Baghiatallah Center, Aiatllah Kashani Street, Kashan
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research, Kashan University of Medical Sciences
Full name of responsible person
Dr.Gholamali Hamidi
Street address
Vice-chancellor for Research, Ghotbe Ravadi Blvd.
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Kashan
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, Kashan 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
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Position
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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