

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 intramuscularly 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

Name

Fatemeh Foroozanfar

Name of organization / entity

Kashan University of Medical Sciences

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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 consumption

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

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

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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

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Vice-chancellor for Research, Ghotbe Ravadi Blvd.

City

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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Foroozanfard

Position

OBS & GYN, IVF Fellowship, 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