

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

A randomized clinical trial on comparing the effect of initiation of letrozole on cycle day 3 with cycle day 5 on ovulation in patients with clomiphene citrate-resistant polycystic ovary syndrom.

Protocol summary

Summary

Objectives: Comparison of the effect of letrozole initiation on ovulation on the cycle day 3 with cycle day 5 in polycystic ovary syndrome patients Design: Randomized, Single blind (Statistical analyst were unaware), Target sample size 70 People of polycystic ovary syndrome patients. The main inclusion criteria to study: Women with previously diagnosed polycystic ovary syndrome and infertility according to Rotterdam criteria; Age between 20-30 years; No previous history of ovarian surgery; Women who did not ovulate on clomiphene citrate in at least 3 previous cycles (did not attain at least 1 follicle equal or more than 18mm on ultrasound scan). The main exclusion criteria from study: Women with infertility of any other etiology; Exposure to cytotoxic drugs; Pelvic radiation therapy. Control group: Letrozole, 3 mg, from third day of cycle for 5 days. Intervention group: Letrozole, 3 mg, from fifth day of cycle for 5 days. Primary outcome measure: Follicle equal or more than 18mm, Before the first dose of letrozole and 3 days after the last dose of letrozole dose, Vaginal ultrasonography; endometrial thickness, Before the first letrozole dose and 3 days after the last letrozole dose, By vaginal ultrasonography; Hormone, Before the first letrozole dose and 3 days after the last letrozole dose, By blood test. Second outcome measure: Pregnancy, At the end of menstrual cycle, By Beta-HCG test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307096467N3**
Registration date: **2014-03-21, 1393/01/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-21, 1393/01/01

Registrant information

Name

Nayereh Ghomian

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1802 2631

Email address

ghomiann@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2010-11-01, 1389/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial on comparing the effect of initiation of letrozole on cycle day 3 with cycle day 5 on ovulation in patients with clomiphene citrate-resistant polycystic ovary syndrom.

Public title

Comparison of the effect of letrozole initiation on ovulation on the cycle day 3 with cycle day 5 in polycystic ovary syndrom patients

Purpose

Treatment

Inclusion/Exclusion criteria

The main inclusion criteria to study: women with previously diagnosed polycystic ovary syndrome (PCOS) and infertility according to Rotterdam criteria; Age between 20-30 years; No previous history of ovarian surgery; Women who did not ovulate on clomiphene citrate in at least 3 previous cycles (did not attain at least 1 follicle equal or more than 18mm on ultrasound scan). The main exclusion criteria from study: Women with infertility of any other etiology; Exposure to cytotoxic drugs; Pelvic radiation therapy

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 Mashhad University of Medical Sciences

Street address

Vice chancellor for Research of Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

City

Mashhad

Postal code

Approval date

2009-11-18, 1388/08/27

Ethics committee reference number

88037

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Follicle equal or more than 18mm

Timepoint

Before the first dose of letrozole and 3 days after the last dose of letrozole dose

Method of measurement

Vaginal ultrasonography

2

Description

Endometrial thickness

Timepoint

Before the first dose of letrozole and 3 days after the last dose of letrozole dose

Method of measurement

Vaginal ultrasonography

3

Description

Testosterone Hormone

Timepoint

Before the first dose of letrozole and 3 days after the last dose of letrozole dose

Method of measurement

Blood test

4

Description

Androstendione Hormone

Timepoint

Before the first dose of letrozole and 3 days after the last dose of letrozole dose

Method of measurement

Blood test

5

Description

Estradiol Hormone

Timepoint

Before the first dose of letrozole and 3 days after the last dose of letrozole dose

Method of measurement

Blood test

Secondary outcomes

1

Description

Pregnancy

Timepoint

At the end of Menstrual cycle

Method of measurement

BHCG test

Intervention groups

1

Description

Control group: Letrozole, 3 mg, from third day of cycle for 5 days

Category

Treatment - Drugs

2

Description

Intervention group: Letrozole, 3 mg, from fifth day of cycle for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

(Montasariéh) IVF Center

Full name of responsible person

Nayereh Ghomian

Street address

(Montasariéh) IVF Center, Akhond-e-Khorasani Street, Mashhad

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ramezani

Street address

Vice Chancellor for Research of Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah Street, Mashhad

City

Mashhad

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 of Mashhad 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

Imam Reza Hospital

Full name of responsible person

Nayereh Ghomian

Position

Gynecologist

Other areas of specialty/work

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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