Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 letrozoel dose, Vaginal ultrasonography; endometrial thickness, Before the first letrozole dose and 3 days after the last letrozole dose, By vaginal ultrasonography; Hormone, Before the fist 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
(Montasarieh) IVF Center
Full name of responsible person
Nayereh Ghomian
Street address
(Montasarieh) IVF Center, Akhond-e-Khorasani Street, Mashhad
City
Mashhad

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
Street address
Imam Reza Hospital, Imam Reza Square, Mashhad
City
Mashhad
Postal code
Phone
+98 51 1802 2608
Fax
Email
ghomiann@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Imam Reza Hospital
Full name of responsible person
Nayereh Ghomian
Position
Associate Professor
Other areas of specialty/work
Street address
Imam Reza Hospital, Imam Reza Square, Mashhad
City
Mashhad
Postal code
Phone
+98 51 1802 2608
Fax
Email

ghomiann@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Imam Reza Hospital
Full name of responsible person
Nayereh Ghomian
Position
Associate Professor
Other areas of specialty/work
Street address
Imam Reza Hospital, Imam Reza Square, Mashhad
City
Mashhad
Postal code
Phone
+98 51 1802 2608
Fax
Email
ghomiann@mums.ac.ir
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