

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Letrozole induction of ovulation in infertile women with Clomiphene resistance

Protocol summary

Summary

Objective: to evaluate the efficacy of Letrozole in induction of ovulation in Clomiphene Citrate (CC)-resistant patients and to compare Letrozole responders with non responders. Inclusion criteria: age 18-39, infertility more than 2 years, normal Thyroid Stimulating Hormone (TSH), spermogram and prolactin and normal Follicle-stimulating hormone (FSH) in the beginning of follicular phase. Exclusion criteria: history of pelvic surgery, presence of adhesions in laparoscopy or hysterosalpingography and presence of any infertility factors except anovulation. Sample size and population under study: 30 patients who referred to Qazvin infertility clinic with polycystic ovary syndrome (PCOS) and unexplained infertility who were resistant to CC. Two months after Clomiphene treatment, Letrozole was given in doses of 2/5 - 7/5 mg (depending on patient response; overall 72 cycles) on days 5-9 of the menstrual cycle. Follicular size was measured by serial vaginal sonography by a specific person followed by administration of Human Chorionic Gonadotropin (hcG) if follicle > 18 millimeter was detected. Ovulation and pregnancy rate and endometrial thickness on day of hcG administration were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010174868N2**
Registration date: **2011-01-31, 1389/11/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-31, 1389/11/11

Registrant information

Name

Khadijeh Elmizadeh

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1333 6001

Email address

khelmizadeh@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Letrozole induction of ovulation in infertile women with Clomiphene resistance

Public title

The effect of Letrozole on Clomiphene resistance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-39, infertility more than 2 years, normal Thyroid Stimulating Hormone (TSH), spermogram and prolactin and normal Follicle-stimulating hormone (FSH) in beginning of follicular phase. Exclusion criteria: history of pelvic surgery,

presence of adhesions in laparoscopy or hystrosalpingography and presence of any infertility factors except anovulation.

Age

From **20 years** old to **37 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Vice Chancellor for Research, Qazvin University of Medical Science

City

Qazvin

Postal code

Approval date

1387-03-08, 769/01/-1107

Ethics committee reference number

28/20/1278

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

presence and number of dominant follicles

Timepoint

4 days after the end of treatment

Method of measurement

vaginal sonography

Secondary outcomes

1

Description

pregnancy

Timepoint

26 days after treatment

Method of measurement

presence of gestational sac in vaginal sonography

Intervention groups

1

Description

Oral letrozol in doses of 2/5, 5 and 7.5 mg (depending on patient response; overall 72 cycles) higher dose was administered to the patients who did not have mature follicle with lower dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Infertility Clinic

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr Saeed Assefzadeh

Street address

Qazvin University of Medical Sciences

City

Qazvin

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 Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr Khadijeh Elmizadeh

Position

Obstetrician & Gynecologist

Other areas of specialty/work

Street address

Kosar Hospital, Taleghani St.

City

Qazvin

Postal code

Phone

+98 28 1223 6380

Fax

Email

khelmizadeh@qums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Khadijeh Elmizadeh

Position

Obstetrician & Gynecologist

Other areas of specialty/work

Street address

Kosar Hospital, Taleghani St.

City

Qazvin

Postal code

Phone

+98 28 1334 7280

Fax

Email

khelmizadeh@qums.ac.ir

Web page address

Person responsible for updating data

Contact

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