Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 folicular phase. Exclusion criteria: history of pelvic surgery, presence of adhesions in laparoscopy or hystrosalpingography 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 Clomiphen 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 Gonaditropin (hcG) if follicle > 18 millimeter was detected. Ovulation and pregnancy rate and endometrial thickness on day of hcG adminstration 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
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Iran (Islamic Republic of)
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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, 5and 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 & Ghynecologist

Other areas of specialty/work

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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