Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparison between infertile women with clomiphene citrate resistant polycystic ovary syndrome (PCOS) undergoing intrauterine insemination (IUI) who receive letrozole and those who did not in prevention of premature luteinizing hormone (LH) surge

Protocol summary

Summary

Intrauterine insemination is the common method to treat infertility in polycystic ovarian syndrome. To achieve success in this method, inducing ovulation by clomiphene in the proper time is required but regarding to its side effects and resistance among some patients, finding alternative drugs is necessary. Due to the common characteristics of clomiphene and letrozole, we aim to evaluate letrozole as an alternative drug to prevent premature secretion of luteinizing hormone. Thus, 140 patients in the range of 18-35 years old, non smoker, suffering from infertility due to polycystic ovary syndrome, resistant to clomiphene, with normal BMI, with no history of endocrine, liver, and kidney diseases, breast cancer, and autoimmune disorders are participated in this study. The patients are divided randomly into two even groups. All patients in the third day of the menstrual period are evaluated by sonography and hormonal tests. After that, 75 units of recombinant follicular stimulating hormone are injected daily to all patients, till the day of human chorionic gonadotropin injection (when at least 2 follicles become larger than 18 mm). In addition, members of group 2 are received 5 mg letrozole daily from 8th day of menstrual cycle till the day of HCG injection. In the day of HCG injection, serum estradiol and luteinizing hormone level are measured and sonography is done. 36 hours after that, artificial fertilization takes place. In this study, the rate of pregnancy and abortion is also evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072814189N1**

Registration date: **2014-06-14, 1393/03/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-14, 1393/03/24

Registrant information

Name

Tahere Bahrami shabahrami

Name of organization / entity

OB and GYN Department, Shiraz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between infertile women with

clomiphene citrate resistant polycystic ovary syndrome (PCOS) undergoing intrauterine insemination (IUI) who receive letrozole and those who did not in prevention of premature luteinizing hormone (LH) surge

Public title
The effects of letrozole in treatment of infertility
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Woman with clomiphene resistant PCOS; Infertility; Normal BMI; 18-35 years old. Exclusion criteria: Diabetes mellitus; Thyroid disease; Endocrinopathies; Breast cancer; Kidney or liver diseases; Autoimmune disorders; Smokers.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
One hundred fourty patients with infertility due to polycystic ovary syndrome are randomly divided into 2 groups of 70. Both groups are equal regarding their age averages. The intervention group (group 2) is given letrozole and control one is received placebo. Since the study was a single blind one, patients do not know which one is medication and which one is placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
School of Medical Sciences, Zand St.
City
Shiraz
Postal code
0000
Approval date
2012-07-08, 1391/04/18
Ethics committee reference number
4106

Health conditions studied

1

Description of health condition studied
polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Stein-Leventhal syndrome

Primary outcomes

1

Description
premature LH surge
Timepoint
third day of experiment and the day of HCG
Method of measurement
measuring LH serum

Secondary outcomes

1

Description
The rate of pregnancy
Timepoint
6-7 weeks of pregnancy
Method of measurement
measuring B-HCG levels in serum

2

Description
Abortion rate
Timepoint
during pregnancy
Method of measurement
measuring B-HCG levels in serum and sonography

Intervention groups

1

Description
Intervention1: Letrozole(Letrozole Soha, Soha Pharmaceutical Company, Karaj, Iran), 2 tab 2.5 mg orally, since the 8th day up to human chorionic gonadotropin injections
Category
Treatment - Drugs

2

Description
Intervention 2: Placebo, 2 tab 2.5 mg orally, since the 8th day up to human chorionic gonadotropin injections
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center of Mother and Child hospital
Full name of responsible person
Tahere Bahrami Shabahrami
Street address
Mother and Child hospital, Quran Sq.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research affairs, Shiraz University of Medical Sciences
Full name of responsible person
Seyed Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand St.
City
Shiraz
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 affairs, Shiraz 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
Department of Obstetrics and Gynecology and Student Research Committee
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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00
Fax
Email
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