

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

Iran (Islamic Republic of)

###### Phone

+98 917 718 1361

###### Email address

emamiy@sums.ac.ir

##### 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 forty 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

Tahere Bahrami Shabahrami

### Position

Resident of Gynecology and Obstetrics

### Other areas of specialty/work

### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Department of obstetrics and gynecology, School of medicine, Shiraz University of Medical Sciences

#### Full name of responsible person

Afsoon Zarei

#### Position

Infertility fellowship

#### Other areas of specialty/work

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## Person responsible for updating data

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#### Name of organization / entity

Department of Obstetrics and Gynecology and Student Research Committee

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Tahere Bahrami Shabahrami

#### Position

Resident of Gynecology and Obstetrics

#### Other areas of specialty/work

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Janbazan Blvd.

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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*