# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Aug 2026

## Effects of letrozole versus clomiphene citrate in combination with recombinant follicle-stimulating-hormone in induction ovulation on intrauterine insemination outcome

## Protocol summary


**Summary**

To investigate the effects of ovulation induction using letrozole and clomiphene citrate in combination with rFSH on outcome of IUI cycles in those suffering from infertility. This was a randomized clinical trial being performed in Shiraz Ghadir hospital and our private infertility clinic, during a 24-months period. 144 women with unexplained infertility were randomly divided into two groups to receive ovarian superovulation. Group A (n=72) received 5-mg per day letrozole (Razak Drug Laboratory, Tehran, Iran) for 5 days from the 5th to the 9th day of cycle while Group B (n=72) received 100-mg per day clomiphene citrate (Razak Drug Laboratory, Tehran, Iran) for 5 days in the same period. All patients received highly purified recombinant FSH (Gonal-f, Serono, Hellas, Puregon, Greece) was injected subcutaneously in a dosage of 150 unit/day from the 8th day of the cycle until the day of hCG administration. Transvaginal sonography was performed on the day 11th of the cycle and according to the size and number of stimulated follicles, rFSH was continued till at least two dominant follicles with size of >18mm were seen. Then 10000 units of human chorionic gonadotropin (hCG) (Choriomon, IBSA, Switzerland) was injected intramuscularly, if serum E2 level was below 2000pg/ml. The endometrial thickness (ET) was measured the same day at its greatest diameter perpendicular to the midsagittal plane at the fundal region of the uterus. A single IUI was performed 36-40 hours after hCG administration. Main outcomes included pregnancy rate, pregnancy rate per cycle, abortion and endometrial thickneness.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2012121810210N2**
Registration date: **2013-01-18, 1391/10/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2013-01-18, 1391/10/29

**Registrant information**

**Name**

Afsun Zarei

**Name of organization / entity**

Shiraz University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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+98 71 1233 2365

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Shiraz University of Medical Sciences

**Expected recruitment start date**

2009-10-01, 1388/07/09

**Expected recruitment end date**

2011-10-01, 1390/07/09

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of letrozole versus clomiphene citrate in combination with recombinant follicle-stimulating-hormone in induction ovulation on intrauterine insemination outcome

**Public title**
Effects of letrozole versus clomiphene citrate in combination with ghonadotropins on IUI cycle in infertile couples
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
We included those 18–40 years old patients who suffered from unexplained infertility, mild male factor (according to World Health Organization criteria), PCOS, cervical factors and mild endometriosis. Exclusion criteria: Cigarette smoking and alcohol abuser (both partner), ovarian hyperstimulation syndrome
**Age**
From **18 years** old to **40 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **144**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double 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 Shiraz University of Medical Sciences
**Street address**
8th Floor, main building of Shiraz University of Medical Sciences, Zand Avenue
**City**
Shiraz
**Postal code**
**Approval date**
2010-09-23, 1389/07/01
**Ethics committee reference number**
CT-90-5947

## Health conditions studied

### 1

**Description of health condition studied**
Infertility and treatment methods
**ICD-10 code**
N97
**ICD-10 code description**
Female infertility associated with anovulation

## Primary outcomes

### 1

**Description**
Pregnancy
**Timepoint**
two weeks after the missed period
**Method of measurement**
measuring level of blood BhCG by ELISA

### 2

**Description**
endometrial thickness
**Timepoint**
when human chorionic gonadotropin (hCG) was injected
**Method of measurement**
measure by transvaginal sonoghraphy at its greatest diameter perpendicular to the midsagittal plane at the fundal region of the uterus

## Secondary outcomes

### 1

**Description**
clinical pregnancy rate
**Timepoint**
4weeks after the missed period
**Method of measurement**
detecting of intrauterine sac by vaginal sonography

### 2

**Description**
multiple pregnancy
**Timepoint**
4 weeks after the missed period
**Method of measurement**
detecting of intrauterine sacs by vaginal sonography

## Intervention groups

### 1

**Description**
Group A patients received 5 mg/day letrozole at days 5-9 menstrual cycle before IUI (n=72). All patients received 150 IU rFSH (Gonal-f, Serono, Hellas, Puregon, Greece) from day 8 until day of hCG administration.10000 IU of

hCG (Choriomon, IBSA, Switzerland) was injected when there were one or two mature follicles with diameter of more than 18 mm. A single IUI was performed 36-40 hours after hCG administration.

**Category**

Treatment - Drugs

**2**

**Description**

Group B received 100-mg per day clomiphene citrate (Razak Drug Laboratory, Tehran, Iran) for 5 days in at days 5-9 menstrual cycle and 150 IU rFSH from day 8 until day of hCG administration.10000 IU of hCG was injected when there were one or two mature follicles with diameter of more than 18 mm. A single IUI was performed 36-40 hours after hCG administration.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Infertility center of Ghadir hospital

**Full name of responsible person**

**Street address**

Infertility Research Center, 4th Floor, Ghadir Hospital, Ghoran Avenue

**City**

Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shiraz university of medical sciences

**Full name of responsible person**

Dr. Gholam Reza Hatam

**Street address**

Shiraz University of Medical sciences, Zand Avenue Sciences, Zand Avenue

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Shiraz university of medical sciences

**Full name of responsible person**

Dr. Afsun Zarei

**Position**

Assistant professor of OB & GYN / Obstetrician and Gynecologist

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

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**Contact**

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infertility fellowship

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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*