Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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

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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