Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the efficacy of clomiphene citrate and letrozole in patients undergoing intra uterine semen injection on the pregnancy rate.

Protocol summary

Summary

The aim of this study is to compare the efficacy of two drugs, Letrozole and Clomiphene Citrate(CC) combined with gonadotropins for ovarian stimulation in women candidate of IUI.160 patients enrolled in this study. Inclusion criteria include of patients candidate of IUI(ovulatory factor; male factor infertility;patients with cervical factor; endometriosis and idiopathic infertility); normal ;pelvic USG and bilateral tubal patency and Exclusion Criteria include of patients with age more than 35; FSH more than 10 on day 3 of menstruation cycle; uterine and adnexal pathology; ovarian cyst on USG; impaired hepatic /renal function; Diabetes mellitus; history of hypersensitivity to the study drug or to its excipients; bilateral tubal obstruction on HSG. Patients randomized to two groups: group A(n=80) (receive Letrozole - gonadotropin) and group B(n=80) (Clomiphene Citrate (CC)-gonadotropin). Group A received 5 mg Letrozole for 5 days from day 3 to 7 of menstrual cycle. In group B Clomiphene Citrate 100 mg was given for 5 days starting from day 3 of menstrual cycle. In addition, in both groups was administered 150 IU human menopausal gonadotropin (hMG)every day, starting on day 8 until human chorionic gonadotropin (hCG) administration. Ovulation was triggered with urinary HCG, when the leading follicle(s) reached 18 mm in diameter. A single IUI was performed 36-40 hours later. The Ovarian stimulation response (E2 levels and number of follicles, clinical pregnancy and endometrial thickness) was outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712141744N1**
Registration date: **2011-10-03, 1390/07/11**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-10-03, 1390/07/11

Registrant information

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Name of organization / entity
Lorestan Medical Science University
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2008-12-20, 1387/09/30

Expected recruitment end date

2009-06-21, 1388/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of clomiphene citrate and letrozole in patients undergoing intra uterine semen injection on the pregnancy rate.

Public title

Clomiphene citrate vs letrozole in patients undergoing intra uterine semen injection

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients candidate of IUI(ovulatory factor; male factor infertility; patients with cervical factor; endometriosis and idiopathic infertility); Normal Pelvic USG and bilateral tubal patency. Exclusion Criteria: Age more than 35; FSH more than 10 on day 3 of menstruation cycle; Uterine and adnexal pathology e.g. leiomyoma; Ovarian cyst on USG., Impaired hepatic /renal function; Diabetes mellitus; History of hypersensitivity to the study drug or to its excipients; Bilateral tubal obstruction on HSG
Age
From **15 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not 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 Lorestan University of Medical Sciences
Street address
Research and technology center, 3rd floor, Lorestan University of Medical Sciences, Pardis(Kamalvand)uUniversity complex, 3 km. road Khoramabad borojerd, Khoramabad
City
khoramabad
Postal code
381351698
Approval date
2009-03-08, 1387/12/18
Ethics committee reference number
9058/200

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
n97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Pregnancy rate
Timepoint
14 days after intra uterine insemination
Method of measurement
Blood test for assay of BHCG

2

Description
Abortion rate
Timepoint
From positive test of BHCG to 20th weeks of gestation
Method of measurement
Pregnancy loss before 20th weeks of gestation determined with ultrasunogeraphy

Secondary outcomes

1

Description
Endometrial thickness
Timepoint
In the time of HCG injection
Method of measurement
Transvaginal ultrasonogeraphy

2

Description
Number of follicles
Timepoint
In the time of HCG injection
Method of measurement
Transvaginal ultrasonograghy

3

Description
Serum estradiol level
Timepoint
In the time of hCG injection
Method of measurement
Blood test(microgram/dl)

Intervention groups

1

Description
Control group (Clomiphene Citrate) : Clomiphene Citrate 100 mg was given for 5 days starting from day 3 of menstrual cycle. In addition, human menopausal gonadotropin (hMG) 150 IU was administered every day, starting on day 8 until human chorionic gonadotropin (hCG) administration. Ovulation was triggered with urinary HCG, when the leading follicle(s) reached 18 mm in diameter. A single IUI was performed 36-40 hours later.

Category
Treatment - Drugs

2

Description
Intervention group (Letrozole) : 5 mg Letrozole for 5 days from day 3 to 7 of menstrual cycle. In addition, human menopausal gonadotropin (hMG) 150 IU was administered every day, starting on day 8 until human chorionic gonadotropin (hCG) administration. Ovulation was triggered with urinary HCG, when the leading follicle(s) reached 18 mm in diameter. A single IUI was performed 36-40 hours later.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Lorestan university of medical sciences

Full name of responsible person
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2

Recruitment center

Name of recruitment center
Kosar infertility center

Full name of responsible person
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City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Lorestan University of Medical Sciences

Full name of responsible person
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Grant name
124409

Grant code / Reference number
1193

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

Title of funding source
Vice chancellor for research, Lorestan 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
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Position
Fellowship of infertility

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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