

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Name

Soheila Akbari

Name of organization / entity

Lorestan Medical Science University

Country

Iran (Islamic Republic of)

Phone

+98 66 1225 0368

Email address

akbari.s@lums.ac.ir

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

khramabad

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 ultrasunography

Secondary outcomes

1

Description

Endometrial thickness

Timepoint

In the time of HCG injection

Method of measurement

Transvaginal ultrasonography

2

Description

Number of follicles

Timepoint

In the time of HCG injection

Method of measurement

Transvaginal ultrasonography

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

Soheila Akbari

Street address

Lorestan University of Medical Sciences,
Pardis(Kamalvand) university complex, 3 km. road
Khoramabad Borojerd, Khoramabad

City

Khoram abad

2

Recruitment center

Name of recruitment center

Kosar infertility center

Full name of responsible person

Maryam Ayazi Roozbahani

Street address

Kosar infertility center, Yegane Ed, Farmanie st.,
Tehran/Iran n

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Lorestan University of
Medical Sciences

Full name of responsible person

Dr.Mohammad Hasan Kaeidi

Street address

Research and technology center, 3rd floor, Lorestan
University of Medical Sciences, Pardis (Kamalvand)
university complex, 3 km. road Khoramabad Borojerd,
Khoramabad

City

Khoramabad

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

Erfan Hospital

Full name of responsible person

Ayazi Roozbahani Maryam

Position

Fellowship of infertility

Other areas of specialty/work

Street address

Erfan hospital, Infertility center, Riazi Bakhshayesh
st.Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2235 9153

Fax

Email

ayaziroz@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lorestan university of medical sciences

Full name of responsible person

Akbari Soheila

Position

Obstetric and Gynecologist

Other areas of specialty/work

Street address

Unit 5, 3rd floor, Yas bldg, Laleh St. Jandarmery Sq.
Khoramabad, Iran

City

Khoramabad

Postal code

6815854395

Phone

+98 66 1225 0368

Fax

+98 66 1225 0367

Email

dr_akbari_s@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ayazi Roozbahani Maryam

Position

Fellowship of infertility

Other areas of specialty/work

Street address

Erfan Hospital, Bakhshayesh St., Saadat Abad,
Tehran, Iran

City

Tehran

Postal code

Iran

Phone

+98 21 2235 9153

Fax

Email

ayazirooz@gmail.com

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