Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison the efficacy of Letrozole-gonadotropins and clomiphene citrate-gonadotropins in Ovarian hyper stimulation of infertile women undergoing intra uterine insemination procedure

Protocol summary

Summary

Patients with unovulation, poly cystic ovary syndrome were included and those with infertility of tubal factor, male factor and age over 35 in women will be excluded. Then 80 subjects will randomly allocated to groups A (Letrozole-gonadotropins) and B (clomiphene citrate-gonadotropins). The patients in the letrozole group (Group A) will receive 5 mg letrozole for 5 days from day 3 of their menstrual cycle. In the CC-gonadotropin group (Group B) clomiphene citrate 100 mg will be given for 5 days starting from day 3 of menstrual cycle. In addition, human menopausal gonadotropin 75 IU will be administered every day, starting on day 6 until human chorionic gonadotropin (hCG) administration. The condition of the ovaries would determined by transvaginal ultrasonography. Sonography will perform every other day from day 10 of the cycle by a single radiologist. When mature leading follicle (s) reached>18 mm in diameter, IM hCG in a dose of 5000-10000 IU will be given and IUI will be performed 36–40 hours later. The main outcome measurement is pregnancy rate. Clinical pregnancy was defined when an intrauterine gestational sac(s) was visible by ultrasonography

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106236868N1**
Registration date: **2011-07-20, 1390/04/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-20, 1390/04/29

Registrant information

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Mahzad Sadaghiani
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences and Health Services

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of Letrozole-gonadotropins and clomiphene citrate-gonadotropins in Ovarian hyper stimulation of infertile women undergoing intra uterine insemination procedure

Public title

Effect of letrozole on ovarian hyper stimulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: unovulation, poly cystic ovary syndrome Exclusion criteria: ifertility with the tubal cause (occlusion of one or both tubes), infertility with sever male cause (less than 10 milion motile sperm), intrauterine masses (myoma and polyp), uterine endometrioma, age over 35 year of women

Age
From **15 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Tabriz university institutional ethics review board

Street address
Azadi avenue, Golgasht street, Vice Chancellor for Research, Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date
2010-07-11, 1389/04/20

Ethics committee reference number
5/4/2762

Health conditions studied

1

Description of health condition studied
infertility

ICD-10 code
N97

ICD-10 code description
Female Infertility

Primary outcomes

1

Description
first follicle generation

Timepoint
one dy another 7-9 days after period

Method of measurement
vaginl ultrasonography

Secondary outcomes

1

Description
pregnancy

Timepoint
18 days after IUI

Method of measurement
by BHCG

Intervention groups

1

Description
first group: letrozole-gonadotropin patients in group letrozole (group A) will receive 5 mg letrozole for five days from day 3 of the menstrual cycle

Category
Treatment - Drugs

2

Description
Second group: clomiphen citrate - gonadotropin In the CC-gonadotropin group (Group B) clomiphene citrate 100 mg will be given for 5 days starting from day 3 of menstrual cycle.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person

Street address

City
tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Mciences

Full name of responsible person
vice chancellor of research

Street address
Tabriz university of medical sciences, Golgasht street, Azadi avenue

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Mciences

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
associte proffesor

Other areas of specialty/work

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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