

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

Name

Mahzad Sadaghiani

Name of organization / entity

Tabriz University of Medical Sciences

Country

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: infertility with the tubal cause (occlusion of one or both tubes), infertility with severe male cause (less than 10 million 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: clomiphene 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 Sciences

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 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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Full name of responsible person

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Position

associate professor

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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