

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effects of letrozole with letrozole in combination with clomiphene on ovulation and pregnancy rate in infertile patients with polycystic ovarian syndrom under Ovulation induction

Protocol summary

Study aim

Comparison the effect of letrozole and clomiphene citrate plus letrozole on the pregnancy rate among infertile patients with polycystic ovarian syndrome undergoing induction of ovulation

Design

Not blind randomized controlled clinical trial with two parallel groups

Settings and conduct

The study place: Infertility Center, Imam Khomeini Hospital, Mazandaran University of Medical Sciences, Sari, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female aged 35 or lower, mild male factor infertility, Poly cystic ovarian syndrome Exclusion criteria: Reluctance to participate in study, body mass index above 27, endocrine disorder including Hypothyroidism, hyperprolactinemia, diminished ovarian reserve

Intervention groups

First intervention group: Letrozole (2.5 mg tablet, Iranian hormones Company) is given twice daily from the third to seventh day of the menstrual cycle. Second intervention group: Clomiphene 2 tablets daily (50 mg tablets, Iran hormones) and Letrozole (2.5 mg tablets, Iran Hormones Company) oral twice daily from the third to seventh day of the menstrual cycle.

Main outcome variables

Pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160815029374N6**
Registration date: **2019-05-24, 1398/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-24, 1402/04/03**

Update count: **1**

Registration date

2019-05-24, 1398/03/03

Registrant information

Name

Marzieh Zamaniyan

Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 5724

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of letrozole with letrozole in combination with clomiphene on ovulation and pregnancy rate in infertile patients with polycystic ovarian syndrom under Ovulation induction

Public title

Effects of letrozole in combination with clomiphene on infertility

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female aged 35 or lower Mild male factor infertility Polycystic ovarian syndrome

Exclusion criteria:

Reluctance to participate in study Body mass index above 27 Endocrine disorder including Hypothyroidism, hyperprolactinemia Diminished ovarian reserve History of pelvic surgery History of ovarian hyperstimulation syndrome Severe male factor infertility Abnormal hysterosalpingography

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **194**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first phase of sampling, after applying the criteria for entry and exclude, samples are selected in an accessible manner. Individuals with the criteria for entering, informed consent are obtained. Then, in the second phase, the samples will be assigned to two groups by blocking method. Create blocks and generate random numbers with Random allocation software. The thirty-two blocks of size six will be produced and arranged by the project manager.

Blinding (investigator's opinion)

Single blinded

Blinding description

The individuals implementing the intervention and evaluating the outcome will not be aware of the allocation of participants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

No. 240, Ground Floor, Joibar Ave., Mazandaran University of Medical Sciences., Sari

City

Sari

Province

Mazandaran

Postal code

4815659769

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.001

Health conditions studied**1****Description of health condition studied**

Disease of genitourinary tract

ICD-10 code

Female inf

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Clinical pregnancy rate

Timepoint

Three weeks after positive B-HCG

Method of measurement

ultrasonography

2**Description**

Ovulation rate

Timepoint

Forty-eight hours after HCG injection

Method of measurement

ultrasonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Letrozole (2.5 mg tablet, Iranian hormones Company) is given twice daily from the third to seventh day of the menstrual cycle.

Category

Treatment - Drugs

2

Description

Intervention group 2: Clomiphene 2 tablets daily (50 mg tablets, Iran hormones) and Letrozole (2.5 mg tablets, Iran Hormones Company) oral twice daily from the third to seventh day of the menstrual cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center, Imam Khomeini Hospital

Full name of responsible person

Marzieh Zamanian

Street address

ground floor, IVF ward, NO 233, Imam Khomeini Hospital, Amirmazandarani Ave

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Marziehzamanian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Marzieh Zamanian

Street address

Third floor, NO 242, Mazandaran University of Medical Sciences, Joybar street

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Marzieh Zamanian

Position

MD, Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Reproductive Health

Street address

Ground floor, IVF ward, NO 233, Imam Khomeini Hospital, Amirmazandarani Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

marzieh zamanin

Position

Asistant professor M.D.

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

marzieh zamanian

Position

assistant professor MD

Latest degree

Specialist

Other areas of specialty/work

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Province

Mazandaran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available