

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison the effect of combining letrozole and gonadotropin with gonadotropin alone on the IVF / ICSI cycle success rate in women with endometriosis

Protocol summary

Study aim

An interventional study that is designed to assess the effect of letrozole and gonadotropin on the success rate of assisted reproductive techniques.

Design

Phase 3 clinical trial with a control group, parallel design, using the random allocation rule is performed on 94 patients.

Settings and conduct

This randomized study will be performed on 94 patients with IVF indication in Yas Hospital with a convenient sampling method. This is a double-blind study, the patient and analyzer do not know the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria include women with pelvic endometriosis and primary infertility, in her first IVF cycle, with 18 to 35-year-old and BMI lower than 30 kg/m², without any uterine diseases and AMH greater than 1 ng/ml. Sperm motility must be at least 20%. Criteria for not entering: women who underwent letrozole or clomiphene therapy for induction ovulation, Sever endometriosis with DIE, Submucosal myoma, and intramural myoma which were detected in TVS, and withdraw to participation.

Intervention groups

On the third day of menstruation, all participants will be evaluated with TVS for measuring endometrial thickness and antral follicle counts. Then, the GnRH agonist will be prescribed and HMG will be initiated when the follicle diameters reach 10 to 12 mm. Their usage will be continued until the ovulation-triggering day, rHCG will be prescribed as a triggering drug when at least two follicles were ≥ 18 mm, and serum E₂ \geq will be 500 pg/mL. On the third day of menstruation, the intervention group will receive letrozole 5 mg orally per day for up to 5 days, while in the control group, participants will receive a placebo on the same days as oral pills.

Main outcome variables

Cinnal-f and HMG dosage, estradiol level, oocyte number and quality, embryo quality, biochemical pregnancy, and clinical pregnancy

General information

Reason for update

Because of the journal request, some parts of the study will be completed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120104008611N12**
Registration date: **2021-03-19, 1399/12/29**
Registration timing: **prospective**

Last update: **2021-06-30, 1400/04/09**

Update count: **1**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

Hamideh Pakniat

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 282242452

Email address

hpakniat@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of combining letrozole and gonadotropin with gonadotropin alone on the IVF / ICSI cycle success rate in women with endometriosis

Public title

Assessment the effect of combining letrozole and gonadotropin on the IVF / ICSI cycle success rate

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with 18 to 35 year-old Body mass index lower than 30 kg/m² In her first IVF cycle Without any uterine diseases Sperm motility of at least 20% in sperm analysis Anti-mullerin hormone greater than 1 ng/ml

Exclusion criteria:

Women who underwent letrozole or clomiphene therapy for induction ovulation Sever endometriosis with DIE Submucosal myoma with any size and intramural myoma greater than 3 cm was detected in transvaginal ultrasound Withdraw to participation

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 47 letters A and 47 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (letrozole) or B (clomiphene) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed double-blind, the participants, and the analyzer do not know the type of treatment. The participants, because of placebo usage, do not know the type of their treatment. Also, the analyzer does not know about the treatment group codes in the SPSS datasheet.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2021-01-23, 1399/11/04

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1399.100

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

Endometriosis

ICD-10 code

N80.9

ICD-10 code description

Endometriosis, unspecified

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

The total prescribed dosage of Cinnal-f, and HMG

Timepoint

Once, at the trigger day

Method of measurement

Will be calculated by gynecologic

2**Description**

The estradiol level

Timepoint

Once, at the trigger day

Method of measurement

Blood sample

3

Description

The oocyte number, and quality

Timepoint

Once, at puncture day

Method of measurement

According to the oocyte puberty degree, the oocyte quality will be determined.

4

Description

The embryo quality

Timepoint

Once, after in vitro fertilization

Method of measurement

According to Gardner system

Secondary outcomes

1

Description

Biochemical pregnancy

Timepoint

Once, 14 days after fetus transfer

Method of measurement

Blood sampling

2

Description

Clinical pregnancy

Timepoint

Once, 6 to 8 weeks after fetus transfer

Method of measurement

Pregnancy sac observation in transvaginal ultrasound

Intervention groups

1

Description

Intervention group: On the third day of menstruation, all participants will be evaluated with TVS for measuring endometrial thickness and antral follicle counts. Then, the GnRH agonist will be prescribed and HMG will be initiated when the follicle diameters reach 10 to 12 mm. Their usage will be continued until the ovulation-triggering day, rHCG will be prescribed as a triggering drug when at least two follicles were ≥ 18 mm, and serum E2 \geq will be 500 pg/mL. On the third day of menstruation, the intervention group will receive letrozole 5 mg orally per day for up to 5 days.

Category

Treatment - Drugs

2

Description

Control group: On the third day of menstruation, all participants will be evaluated with TVS for measuring endometrial thickness and antral follicle counts. Then, the GnRH agonist will be prescribed and HMG will be initiated when the follicle diameters reach 10 to 12 mm. Their usage will be continued until the ovulation-triggering day, rHCG will be prescribed as a triggering drug when at least two follicles were ≥ 18 mm, and serum E2 \geq will be 500 pg/mL. On the third day of menstruation, the control group will receive a placebo orally per day for up to 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Hamideh Pakniat

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

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Tehran

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Postal code

1597856511

Phone

+98 21 8608 9089

Email

pakniat110@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Sahraiyen

Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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Province

Tehran

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1416634793

Phone

+98 21 8163 3689

Email

vcr@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Hamideh Pakniat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hamideh Pakniat

Position

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Pakniat, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Pakniat

What processes are involved for a request to access data/document

Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Pakniat.

Comments