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 ≥ 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)
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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 ≥ 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 ≥ 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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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. Sahraiyan
Street address
Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran
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Postal code
1416634793
Phone
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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

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Position
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Person responsible for updating data

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Full name of responsible person
Hamideh Pakniat
Position
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Latest degree
Specialist
Other areas of specialty/work
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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