

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effect of letrozole addition to GnRH-antagonist protocol on IVF/ICSI cycle outcome in women with endometriosis

Protocol summary

Study aim

Determination of the effect of letrozole addition to GnRH-antagonist protocol on IVF/ICSI cycle outcome in women with endometriosis

Design

This study is a double-blinded parallel clinical trial

Settings and conduct

This study will be conducted on women aged 18-42 years with endometriosis-related infertility candidate for IVF/ICSI referring to the infertility clinic of Arash Women's Hospital after receiving written consent. The eligible individuals will be randomized into one of the following two groups: 1-intervention group: daily gonadotropins from cycle day 2 and co-treatment with letrozole 2.5 mg twice a day from day 3 until 5 days. GnRH antagonist (Cetrotide 0.25 mg or ganirelix 0.25 mg) will be started when the size of the largest follicle reaches 14 mm. 2-Control group: adding placebo to the antagonist protocol. Follicular growth will be monitored every three days by transvaginal sonography. When at least two follicles with a size of 17 mm were observed, 10,000 units of HCG will be injected for triggering and ultimate maturation of the oocyte. the ovarian puncture will be performed 34-36 hours after hCG injection.

Participants/Inclusion and exclusion criteria

In this study, women aged 18-42 with a normal BMI undergoing ICSI-IVF because of endometriosis induced infertility will be included in the study and women with male factor infertility, decreased ovarian reserve, repeated IVF failure, Medical diseases, congenital anomalies of the uterus and candidate for donation will be excluded.

Intervention groups

Adding letrozole to the antagonist cycle in the intervention group and adding placebo to the cycle in the control group

Main outcome variables

Endometrial pattern and thickness, MII oocyte, embryo quality, chemical pregnancy rate, clinical pregnancy rate,

implantation rate and ongoing pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150310021420N4**

Registration date: **2018-07-13, 1397/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-13, 1397/04/22**

Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name

Maryam Farid Mojtahedi

Name of organization / entity

Arash women hospital, clinic for infertility, Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 8755

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of letrozole addition to GnRH-antagonist protocol on IVF/ICSI cycle outcome in women with endometriosis

Public title
The effect of letrozole on treatment of endometriosis-related infertility

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 consent to participation aged between 18 to 42 years
 BMI ranged between 18.5 to 24.9 endometriosis-induced infertility and ICSI-IVF candidate Endometriosis diagnosed by pathology reports
Exclusion criteria:
 Sever Male Factor Evidence of reduced ovarian reserve (FSH levels above 10, AMH levels lower than 1, AFC reduction) Endocrine disorders (diabetes - Thyroid diseases - Hyperprolactinemia - Hypothalamic amenorrhea and ...) Known case of medical and immunologic diseases (lupus, rheumatoid arthritis, antiphospholipid syndrome, cardiovascular, liver and kidney disease) Congenital anomalies of the uterus and endometrial cavity problems (bicorn or Unicorn uterus, Asherman syndrome, myoma, polyps, etc.) Candidate for donation (egg donation and surrogacy) Recurrent IVF failures (more than three consecutive failures)

Age
From **18 years** old to **42 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
According to Stratified Block randomization, the samples will be divided into two groups of intervention and control (based on the PCOS variable), the number of blocks will be 6. The random allocation list is solely available to the epidemiologist. For Concealment of the random allocation process, treatments will be written on 144 cards, respectively. then the cards are placed inside sealed envelopes. When the physician announces the eligibility of a patient, the methodologist will provide the physician with the envelope.

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

Ethics committee of School of Medicine - Tehran
University of Medical Sciences

Street address

Poorsina st - Qods st - enghelab st - Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.075

Health conditions studied

1

Description of health condition studied

endometriosis-related infertility

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

Primary outcomes

1

Description

Endometrial Line Thickness (EL)

Timepoint

Triggering day

Method of measurement

Trans vaginal sonography (TVS)

2

Description

M II oocytes

Timepoint

after oocyte retrieval

Method of measurement

Questionnaire

3

Description

Embryo Quality
Timepoint
after ICSI
Method of measurement
Report sheet of Embryology ward

4

Description
Chemical Pregnancy
Timepoint
2 weeks after ET
Method of measurement
BHCG Test

5

Description
Clinical pregnancy
Timepoint
Presence of pregnancy sac in ultrasound 5 weeks after ET
Method of measurement
Trans vaginal sonography (TVS)

Secondary outcomes

1

Description
Ongoing pregnancy
Timepoint
Ongoing pregnancy until 12 weeks of gestation
Method of measurement
sonography

Intervention groups

1

Description
Intervention group: Adding letrozole at a dose of 2.5 mg per day from the third day of the cycle to the antagonist treatment cycle for 5 days.
Category
Treatment - Drugs

2

Description
Control group: Antagonist protocol without placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person

Dr Maryam Farid-Mojtahedi
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
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1653915981
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad Ali Sahraian
Street address
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Phone
+98 21 8163 3619
Fax
+98 21 8163 3611
Email
rmo@tums.ac.ir
Web page address
<http://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

Maryam Farid-Mojtahedi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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1653915981

Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available