Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Gonadotropin-releasing hormone (GnRH) agonist vs GnRH antagonist in stimulation protocol on ART outcomes in infertile endometriosis patients

Protocol summary

Study aim
Comparative study of Gonadotropin-releasing hormone (GnRH) agonist and antagonist protocol on IVF outcomes in endometriosis patients

Design
Patients are recruited in two parallel groups. allocation is done with block randomization for groups. participants and physicians are not blinded

Settings and conduct
Patients who refer to Taleghani Hospital's Infertility Center due to infertility and endometriosis are first checked. Then the study method is explained to them. Patients and doctors were not blinded to the type of treatment.

Participants/Inclusion and exclusion criteria
Patients aged between 20-40 years, patients with endometriosis without previous history of endometriosis surgery, patients with anti-mullerian hormone (AMH) level>1 ng/ml, Antral follicle count (AFC) number>5, patients with Ca125<200, and no untreated endocrine disease were included in the study. exclusion criteria: Patients with structural problems of the uterus such as polyps or fibroids, patients with genetic disorders, and patients with a history of poor response to stimulation in previous cycles and a history of Ovarian hyperstimulation syndrome (OHSS)

Intervention groups
In the agonist protocol, the GnRH agonist starts from the previous mid-luteal cycle (on a daily basis), and from the second day of menses, gonadotropin is started for the patient and we follow and the trigger should be HCG. In the antagonist protocol, the cycle is started on the second day of menses in endometriosis patients and based on the number of AFC and serum AMH levels as well as the age of the patient and the answers obtained in the previous cycles, if necessary, the treatment is started with gonadotropin and followed by ultrasound. It is done with an HCG trigger.

Main outcome variables
The quality and number of oocytes and embryos

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230403057803N1**
Registration date: **2023-04-24, 1402/02/04**
Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**
Update count: **0**

Registration date
2023-04-24, 1402/02/04

Registrant information

Name
mitra nemati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 2560

Email address
mithraa.nemati@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Gonadotropin-releasing hormone (GnRH) agonist vs GnRH antagonist in stimulation protocol on ART outcomes in infertile endometriosis patients

Public title
GNRH agonist vs GNRH antagonist in infertility treatment.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged between 20 and 40 years Patients with endometriosis without a history of endometriosis surgery Patients with anti-mullerian hormone (AMH) level > 1ng/ml Number of antral follicle count (AFC)>5 Patients with Ca125<200 Absence of untreated endocrine disease

Exclusion criteria:
Patients with uterine structural problems such as polyps or fibroids Patients with genetic disorders Patients with a history of poor response to stimulation in previous cycles History of ovarian hyperstimulation syndrome (OHSS)

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization in which patients are randomly divided into two groups of 60 patients using a table of random numbers. An independent researcher makes random allocation cards using computer-generated random numbers. He keeps the original random allocation sequences in an inaccessible third place and works with a copy. Since the executors can get confused with the original coding of A and B later, the allocator should record exactly what these codes mean to avoid further confusion. Next, we print it out and put each of the sheets one by one into each envelope. The allocation sequence was concealed from the researcher (JR) enrolling and assessing participants in sequentially numbered, opaque, sealed, and stapled envelopes.

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
Ethic commitee of faculty of medicine. Shahid Beheshti University of Medical Sciences

Street address
Taleghani hospital, Arabi street, Velenjak, Chamran Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1985711151

Approval date
2023-03-13, 1401/12/22

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.893

Health conditions studied

1

Description of health condition studied
Infertility in endometriosis

ICD-10 code
N80

ICD-10 code description
Endometriosis

Primary outcomes

1

Description
Oocyte and embryo count and quality

Timepoint
One month after the treatment (it is not possible to compare before and after the treatment within groups. we can only compare the two groups after the treatment.)

Method of measurement
Embryologist assessment based on microscopic criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the antagonist protocol, Cinnal-f® (Follitropin alfa) is injected subcutaneously daily from the

second day of the cycle, and then when the follicle size reaches 14 mm and at most on day 6, Cetronax 250 mg is injected subcutaneously (Ronak Pharmaceutical Co). This medicine continues with HCG until the trigger day.

Category

Treatment - Drugs

2

Description

Control group: In the agonist protocol, from the 21st day of the previous cycle, Sinnafact with a dose of 50 mg (CinnaGen Co) is injected subcutaneously daily, and from the second day of the cycle, Cinnal-f® (with a dose depending on age and weight and the patient's ovarian reserve) and Cinnafact 20mg are injected daily and subcutaneously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

IVF center, Taleghani hospital

Full name of responsible person

Sedighe Hosseini

Street address

Taleghani hospital, Shahid Arabi Street, Velenjak, Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Email

taleghanihospital@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedighe Hosseini

Street address

Shahid Arabi street

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Email

taleghanihospital@sbmu.ac.ir

Grant name

IVF center of Shahid Beheshti University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedighe Hosseini

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Shahid Arabi Street

City

Tehran

Province

Tehran

Postal code

1985711161

Phone

+98 21 2303 1111

Email

taleghanihospital@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Nemati

Position

fellowship assisstant

Latest degree

Specialist

Other areas of specialty/work
Gynecology and Obstetrics
Street address
Shahid Arabi Street
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1111
Email
mithraa.nemati@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mitra Nemati
Position
Fellowship Assisstant
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Shahid Arabi Street
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1111
Email
mithraa.nemati@gmail.com

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
Yes - There is 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
It is not decided yet
When the data will become available and for how long
It is not decided yet
To whom data/document is available
It is not decided yet
Under which criteria data/document could be used
It is not decided yet
From where data/document is obtainable
It is not decided yet
What processes are involved for a request to access data/document
It is not decided yet
Comments