Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the pregnancy outcome in the GnRH antagonist protocol with pretreatment in the luteal phase (including oral estradiol with or without GnRH antagonist) in comparison with the microdose GnRH agonist protocol in poor responder patients (Poseidon 3) in patients undergoing fertility treatment at the Milad Infertility Center.(randomized clinical trial)

Protocol summary

Study aim

Comparison of pregnancy rate of GnRH antagonist protocol with oral estradiol pretreatment with or without GnRH antagonist and GnRH flare agonist microdose protocol in Poseidon 3 women

Design

Random assignment to the intervention and control groups in the form of a double-blind random block design with a sample size of 105

Settings and conduct

This study is conducted at Milad Infertility Center on 105 women under 35 years of age with low ovarian reserves (AMH<1.2 and AFC<5). Participants randomly will be divided into 3 groups using the permutation block method. Sealed envelopes will be used to hide the allocation. The patient-analyst is unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

inclusion criteria : Infertile women candidates for IVF under 35 years of age with regular cycles low ovarian reserves (AMH<1.2 and AFC<5) Exclusion criteria: Male factor of infertility (severe), Having moderate to severe endometriosis Having adenomyosis, Having uterine myoma other than subserous myoma with any moma less than 4 cm BMI>30

Intervention groups

In the first group, from the 19th day of the previous cycle, oral estradiol is prescribed at a dose of 4 mg daily for 10 days. Gonadotropins start on the third day of the next period. In the second group, in addition to oral estradiol, cetrorelix subcutaneous ampoule will be added for 3 days from the 26th day of the cycle. Gonadotropins start on the third day of the next period. Control group: First, on the 4th day of the cycle, for 2 weeks, OCP is prescribed, and on the second day of the next menstrual cycle, the GnRH agonist with a dose of 50 micrograms of CinnaFactsubcutaneously, and on the third day of the menstrual cycle, gonadotropins are started.

Main outcome variables

number of oocytes, M2 oocytes, embryos, chemical pregnancy, clinical pregnancy, and Ongoing pregnancy. Abortion rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041503N8**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name

Malihe Mahmoudinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2024-11-21, 1403/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the pregnancy outcome in the GnRH antagonist protocol with pretreatment in the luteal phase (including oral estradiol with or without GnRH antagonist) in comparison with the microdose GnRH agonist protocol in poor responder patients (Poseidon 3) in patients undergoing fertility treatment at the Milad Infertility Center.(randomized clinical trial)

Public title
Evaluation of pregnancy success in infertile people with low ovarian reserve and less than 35 years old in IVF method with two different protocols.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women candidates for IVF under 35 years of age with regular cycles and low ovarian reserves (AMH<1.2 and AFC<5)
Exclusion criteria:
Male factor of infertility (severe), having moderate to severe endometriosis, having adenomyosis, or having uterine myoma other than subserous myoma with any syzymoma less than 4 cm, BMI>30
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
0
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, permutation blocks method was used to generate the sequence of random assignment of people to the studied groups. Random allocation sequence of people was done using Random Allocation Software and random block size. Therefore, the first person is assigned to the control group, the second person to intervention group 2, the third person to the control group, etc. and this process continues until all samples are assigned. The characteristic of this method is that the two study groups will have equal numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Sealed envelopes are used to hide the allocation. Based on the order of arrival of the research units, the envelopes are opened in order and the allocated group is revealed. The patient and the analyst are unaware of the type of treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad university of medical sciences Ethics committee
Street address
Imam Reza Hospital, Imam Reza St., Mashhad, Iran
City
mashhad
Province
Razavi Khorasan
Postal code
9178943791
Approval date
2023-10-23, 1402/08/01
Ethics committee reference number
IR.MUMS.IRH.REC.1402.148

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N98.3
ICD-10 code description
Complications of attempted introduction of embryo in embryo transfer

Primary outcomes

1

Description
Total number of oocytes
Timepoint
Total number of M2 oocytes

Method of measurement
After picking up and laboratory examination

2

Description
Chemical pregnancy
Timepoint
n 2 week after embryo transfer
Method of measurement
BHCG

3

Description
The rate of clinical pregnancy
Timepoint
6 weeks after embryo transfer
Method of measurement
Sonography

4

Description
ongoing pregnancy
Timepoint
Continue pregnancy for up to 20 weeks
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first group, from the 19th day of the previous cycle, oral estradiol is prescribed at a dose of 4 mg daily for 10 days. Gonadotropins start on the third day of the next period.
Category
Treatment - Drugs

2

Description
Intervention group: In the second group, in addition to oral estradiol, cetrorelix (cetrotide 0.25 mg) subcutaneous ampoule will be added for 3 days from the 26th day of the cycle.Gonadotropins start on the third day of the next period.
Category
Treatment - Drugs

3

Description
Control group: First, on the 4th day of the cycle, for 2 weeks, OCP is prescribed, and on the second day of the next menstrual cycle, the GnRH agonist with a dose of 50 micrograms of CinnaFact (buserelin 5.5mg)) subcutaneously, and on the third day of the menstrual cycle, gonadotropins are started.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Infertility center
Full name of responsible person
Ezat Shabani
Street address
Imam Reza Hospital, Imam Reza St., Mashhad, Iran
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Email
shabanie960@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
malihe mahmoudinia
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
malihe mahmoudinia
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ezat Shabani
Position
Assistant of infertility fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Position
Assistant of infertility fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
I'm looking into the matter
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
Not applicable
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