# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

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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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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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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
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**Position**
Assistant Professor
**Latest degree**
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## Person responsible for scientific inquiries

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Assistant of infertility fellowship
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## Person responsible for updating data

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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