

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of pregnancy rate after frozen embryo transfer in two methods of endometrial preparation: using GnRH agonist together with letrozole and GnRH agonist alone in women with recurrent implantation failure

Protocol summary

Study aim

The effect of GnRH agonist with letrozole in frozen transfer in women with recurrent implantation failure

Design

In this randomized clinical trial involving 60 women (18-40 years), two groups were randomly assigned. - Method used to generate random allocation sequence by mentioning the name of the software or site used: Computer random assignment list produced with PASS software.

Settings and conduct

This study is conducted at the Milad Infertility Center on infertile women with a history of two failed transfers. In one group, GnRH agonist, and letrozole were used two months before the transfer, and in the other group, the GnRH agonist protocol alone was used in the frozen embryo transfer. Blinding was not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women (18-40 years) with a history of at least two failed embryo transfers and at least 5 good-quality embryos have been transferred. lack of confirmed endometriosis and Endometrioma. Exclusion criteria include: patient dissatisfaction during treatment to continue the study and the presence of pathology endometrial

Intervention groups

Intervention group: In the intervention group, treatment with GnRH agonist, decapeptyl ampoule with a dose of 3.75 mg intramuscular (Varian Pharmed Pharmaceutical Company) along with letrozole 5 mg daily (Iran Hormone Pharmaceutical Company) is prescribed for two months and during the next period if suppression of ovaries and uterus is confirmed, treatment with oral estradiol is started. In the control group, the GnRH agonist (decapeptyl intramuscular injection with a dose of 3.75 mg) was started on the 21st day of the previous cycle,

and the treatment with estradiol was prescribed on the second day of menstruation.

Main outcome variables

chemical pregnancy rate, Clinical pregnancy rate, ongoing pregnancy rate, and abortion rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041503N7**

Registration date: **2023-11-02, 1402/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-02, 1402/08/11**

Update count: **0**

Registration date

2023-11-02, 1402/08/11

Registrant information

Name

Malihe Mahmoudinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3882 9878

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2024-03-29, 1403/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregnancy rate after frozen embryo transfer in two methods of endometrial preparation: using GnRH agonist together with letrozole and GnRH agonist alone in women with recurrent implantation failure

Public title

Effect of GnRH agonist and letrozole treatment in women with recurrent implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile women (18-40 years) with a history of at least two failed embryo transfers and at least 5 good-quality embryos have been transferred. Document of the normal uterine cavity normal test of TSH, Prolactin and thrombophilia lack of confirmed endometriosis and Endometrioma Lack of fibroma greater than 4 centimeters.

Exclusion criteria:

patient dissatisfaction during treatment to continue the study The presence of pathology endometrial

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **30**

Infertile patients with a history of two unsuccessful transfers

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. -In this randomized clinical trial involving 60 women (18-40 years), two groups were randomly assigned. Randomization will be by block method. In this study, 6 quadruple blocks (AABB(1)-ABAB(2)-ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) will be the sampling guide. Then the list of blocks will be written and numbers will be assigned to them, then random numbers between 1 to 6 (eg 1, 4, 5, etc.) will be selected using the numbers site.

<http://www.graphpad.com/quickcalcs/index.cfm>

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**

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

2020-10-29, 1399/08/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.462

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**

chemical pregnancy rate

Timepoint

2 week after embryo transfer

Method of measurement

BHCG

2**Description**

The rate of clinical pregnancy

Timepoint

6 weeks after embryo transfer

Method of measurement

Sonography

3

Description

ongoing pregnancy

Timepoint

Continue pregnancy for up to 12 weeks

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, treatment with GnRH agonist, decapeptyl ampoule with a dose of 3.75 mg intramuscular (Varian Pharmed Pharmaceutical Company) along with letrozole 5 mg daily (Iran Hormone Pharmaceutical Company) is prescribed for two months and during the next period if suppression of ovaries and uterus are confirmed (including absence of cysts and thickness of the uterus less than 5 mm), treatment with oral estradiol is started.

Category

Placebo

2

Description

Intervention group: in the control group, the GnRH agonist (decapeptyl intramuscular injection with a dose of 3.75 mg) will be started on the 21st day of the previous cycle, and estradiol will be prescribed from the second day of menstruation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility center

Full name of responsible person

malihe mahmoudinia

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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