

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

A clinical trial to compare the frozen embryo transfer (FET) via letrozole and recombinant human FSH (rhFSH) induction with GnRH agonist and estradiol valerate in infertile women with unsuccessful embryo transfer history

Protocol summary

Study aim

To compare the frozen embryo transfer (FET) via letrozole and recombinant human FSH (rhFSH) induction with GnRH agonist and estradiol valerate in infertile women with unsuccessful embryo transfer history.

Design

In this pragmatic single-blind, controlled clinical trial, 142 women with unsuccessful embryo transfer history were assigned into parallel groups using the table of random numbers in a community-based setting.

Settings and conduct

Women with unsuccessful embryo transfer history at the Milad Fertility Clinic, Mashhad, were chosen. In this single-blind study, the data collector was blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 22-40 years; history of more than twice unsuccessful embryo transfer; the male does not have severe infertility. Exclusion criteria: Severe endometriosis stage 3 and 4; fibroma >4 cm; non-frozen-thawed embryo transfer; necrotic embryonic.

Intervention groups

The intervention group will receive 2.5 mg of letrozole in cycle day 3 for 5 days and 75 ml of IU rhFSH in cycle day 9. The control group will receive 500 µg of GnRH agonist in cycle day 21 and 4 mg of estradiol valerate in next cycle day 3.

Main outcome variables

Evaluation and comparison of clinical pregnancy two and six weeks after embryo transfer in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181109041597N1**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

Elnaz Zohdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3853 4021

Email address

zohdie961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the frozen embryo transfer

(FET) via letrozole and recombinant human FSH (rhFSH) induction with GnRH agonist and estradiol valerate in infertile women with unsuccessful embryo transfer history

Public title

The frozen embryo transfer in infertile women with unsuccessful embryo transfer history.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range of 22-40 years History of more than twice unsuccessful embryo transfer The male does not have severe infertility

Exclusion criteria:

Severe endometriosis stage 3 and 4 Fibroma >4 cm Non-frozen-thawed embryo transfer Necrotic embryonic

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Totally 142 women with unsuccessful embryo transfer history at the Milad Fertility Clinic, Mashhad, were chosen. The participants were allocated into two groups of intervention and control using the table of random numbers based on computer programs

Blinding (investigator's opinion)

Single blinded

Blinding description

Women with unsuccessful embryo transfer history at the Milad Fertility Clinic, Mashhad, were chosen. In this single-blind study, the data collector was blind to group assignment and the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2018-11-01, 1397/08/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.412

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

Two and six weeks after embryo transfer

Method of measurement

Human chorionic gonadotropin (hCG) test and transvaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 2.5 mg of letrozole in cycle day 3 for 5 days and 75 ml of IU rhFSH in cycle day 9.

Category

Treatment - Other

2

Description

Control group: The control group will receive 500 µg of GnRH agonist in cycle day 21 and 4 mg of estradiol valerate in next cycle day 3.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Fertility Clinic

Full name of responsible person

Elnaz Zohdi

Street address

Milad Fertility Clinic, East Razi Street

City

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Province

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9135913556

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Email

zohdie961@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street

City

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9195965919

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+98 51 3841 1538

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vcresearch@mums.ac.ir

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

Elnaz Zohdi

Position

Resident

Latest degree

Medical doctor

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

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

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

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Elnaz Zohdi provides the analysis code to the applicants via email: zohdie961@mums.ac.ir

What processes are involved for a request to access data/document

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments