

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the consequences of freezing embryo transfer in infertile women with tamoxifen and recombinant gonadotropin group with GNRH agonist group and estradiol valerate

Protocol summary

Study aim

Comparison of the consequences of freezing embryo transfer (chemical and clinical pregnancy) in infertile women in the induction group with tamoxifen and recombinant gonadotropin with the GNRH agonist group and estradiol valerate

Design

controlled clinical trial, with parallel groups, one-way blind, randomized, on 192 patients. The rand function of the Excel software was used for randomization.

Settings and conduct

Milad Hospital

Participants/Inclusion and exclusion criteria

Infertile women (18-42 years old) who go to Milad Infertility Center for freezing embryo transfer have a history of two or more failed embryo transfer. Couples who are not severely infertile or TESE candidate (Testicular Sperm Extraction) may not have severe grade 3 and 4 endometriosis, may not have fibroids > 4 cm, may not be candidates for fresh embryo transfer, and may not have primary and secondary amenorrhea.

Intervention groups

Tamoxifen 20 mg twice daily from the third day of the cycle for five days, and HMG is given at a dose of 150 mg daily on days 6 and 8.

Main outcome variables

The frequency of chemical and clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041503N3**

Registration date: **2020-06-25, 1399/04/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-25, 1399/04/05**

Update count: **0**

Registration date

2020-06-25, 1399/04/05

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

2019-05-22, 1398/03/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the consequences of freezing embryo transfer in infertile women with tamoxifen and recombinant gonadotropin group with GNRH agonist group and estradiol valerate

Public title

Comparison of embryo transfer in two different protocol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Infertile women (18-42 years old) who go to Milad Infertility Center for transfer freezing embryo with a history of two or more failed embryo transfer. Couples who are not severely infertile or TESE candidate (Testicular Sperm Extraction) . may not have severe grade 3 and 4 endometriosis. may not have fibroids> 4 cm. may not be candidates for fresh embryo transfer. and may not have primary and secondary amenorrhea.

Exclusion criteria:
 Failure to remove the fetus from the freezer, , necrotic embryo patient dissatisfaction during treatment to continue the study

Age
 From **18 years** old to **42 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Data analyser

Sample size
 Target sample size: **96**

Randomization (investigator's opinion)
 Randomized

Randomization description
 -Simple randomization. -In this randomized clinical trial involving 192 women (18-42 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. -We have no way to hide Allocation Concealment.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 The analyst will be unaware of the intervention and control groups. It is not possible for patients to be blind because the type of medication prescribed to patients (injectable and oral) varies in two groups.

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

Vice chancellor of Research, Mashhad university of Medical Sciences, Mashhad University of Medical Sciences ,University Avenue.Mashhad

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Razavi Khorasan

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9138813944

Approval date

2019-01-29, 1397/11/09

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.003

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

Secondary outcomes

1

Description

ongoing pregnancy

Timepoint

Continue pregnancy for up to 12 weeks

Method of measurement

Transvaginal ultrasound

Intervention groups

1

Description

The intervention group included 96 patients who were given 20 mg of tamoxifen twice daily for the third day of the cycle for five days, and HMG was given at 150 mg daily on days 6 and 8. Subsequent patient evaluation is performed on days 9 to 10 of the cycle with transvaginal ultrasound to measure the diameter of the follicle and the thickness of the endometrium. And if the thickness of the endometrium is 8 mm and the diameter of the dominant follicle is 18 mm, HCG10000 IU is injected to induce ovulation. 36 hours after HCG injection, the progesterone utrogestan (Besrogestan, Besins, Brussels, Belgium) 200 mg vaginal 200 mg three times daily or 100 mg endometriosis three times a day. Progesterone continues until the pregnancy test results. Endometrial thickness per day HCG Is checked.

Category

Treatment - Drugs

2

Description

Control group: In the control group, the OCP receives for 21 days, and on the 21st day of the cycle, one-third of the 3.75 decapeptil is prescribed. On the second day of the next cycle, estradiol is started at a dose of 4 mg and after three days it is converted to 6 mg. On the ninth day, ultrasound is performed in terms of endometrial thickness and increases to a maximum of 8 mg per day as needed. 100 ml endometrium is started three times a day. Progesterone is given for 5 days for blastocyst.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility center

Full name of responsible person

Malihe Mahmoudinia

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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

Maliheh Mahmoudinia

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Nayyereh Khadem

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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