

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of Hormone replacement therapy with ovarian stimulation as endometrial preparation protocols for frozen thawed embryo transfer

#### Protocol summary

##### Study aim

Using drugs with less side effects (letrozole and gonadotropin instead of estradiol) to prepare the uterus for frozen embryo transfer

##### Design

The clinical trial has a control group and a parallel group that is blinded on one side and individual and block randomization with RAS software on 108 patients.

##### Settings and conduct

This study is a one-sided blind clinical trial that is performed in the frozen embryo transfer cycle of patients referred to the infertility center of Mahdieh Hospital in Tehran. Patients will be randomly assigned to two groups receiving estradiol and the group receiving letrozole and HMG.

##### Participants/Inclusion and exclusion criteria

Intervention group: Women with frozen embryos who are in the embryo transfer cycle and are treated with letrozole and gonadotropin to prepare the uterine endometrium for embryo transfer, and when the thickness of the endometrium reaches the desired size (7 mm) and a dominant follicle Ovulation stimulation is done and depending on the age of the embryo, embryo transfer is done after a few days. Control group: women candidates for the frozen embryo transfer cycle are subjected to the usual treatment with estradiol tablets to prepare the endometrium to the desired size (7 mm) and the embryo transfer is performed.

##### Intervention groups

Intervention group: 18-42-year-old frozen embryo transfer candidate women without uterine anatomical disorders who are treated with letrozole and gonadotropin to prepare the uterine endometrium. Control group: 18-42-year-old frozen embryo transfer candidate women without uterine anatomical disorders. which are treated with estradiol pills to prepare the endometrium for embryo transfer.

##### Main outcome variables

Chemical and clinical pregnancy. abortion Appropriate

thickness of the endometrium (cancellation or not of the cycle)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230514058176N1**

Registration date: **2023-06-19, 1402/03/29**

Registration timing: **prospective**

Last update: **2023-06-19, 1402/03/29**

Update count: **0**

##### Registration date

2023-06-19, 1402/03/29

##### Registrant information

##### Name

samira azimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5506 2628

##### Email address

drazimi48@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-21, 1402/03/31

##### Expected recruitment end date

2024-03-18, 1402/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Hormone replacement therapy with ovarian stimulation as endometrial preparation protocols for frozen thawed embryo transfer

**Public title**

Comparison of Hormone replacement therapy with ovarian stimulation as endometrial preparation protocols for frozen thawed embryo transfer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women referring to Mahdijeh infertility treatment center aged between 18 and 42 years who have frozen embryos  
Have a normal uterine structure  
Have a healthy endometrium without endometrial polyps or submucosal myoma

**Exclusion criteria:**

anatomical malformation of uterus ; unicorn. bicorn  
underlying disease like diabet. thyroid . cardiovascular.  
immun disease

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **184**

More than 1 sample in each individual

Number of samples in each individual: **92**

patient candidated for frozen embryo transfer

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study will be done in a randomized block fashion. Individual randomization unit is considered. RAS statistical software will be used for block randomization and also for determining the sequence of blocks. All patient information will be recorded in spss26 software.

**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**

Ethic committee of Shahid Beheshti University of Medical Science

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1419943471

**Approval date**

2023-04-30, 1402/02/10

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1402.084

**Health conditions studied****1****Description of health condition studied**

The method of endometrial preparation in the frozen embryo transfer cycle

**ICD-10 code**

N97.4

**ICD-10 code description**

Female infertility associated with male factor

**Primary outcomes****1****Description**

Endometrial thickness: The appropriate thickness of the endometrial layer of the uterus for embryo transfer, which is better to be above 6 to 7 mm to prepare for embryo transfer.

**Timepoint**

The thickness of the endometrium is measured before the start of the treatment and 7-14 days after the intervention.

**Method of measurement**

Endometrial thickness is measured by transvaginal ultrasound.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Infertile women referred to the infertility treatment center of Mahdijeh Hospital, who are in the cycle of frozen embryo transfer, and in order to

prepare the endometrium on the third day of menstruation, letrozole tablets (Latrax 2.5 mg, Aburihan Pharmaceuticals) were taken once a day at night for 5 days. Human menopausal gonadotropin (HMG 75 IU) ampoule will be injected intramuscularly once a day for three days. Then a control ultrasound is performed and if the follicle is 17 to 22 mm and the thickness of the endometrium is 6 to 7 mm, the human chorionic gonadotropin ampoule will be administered. (HCG 5000 IU) is injected intramuscularly. 36 hours later, 50 mg progesterone ampoule (Abourihan Company) will be injected intramuscularly for 3 days in the case of three-day-old embryos and 5 days in the case of 5-day-old embryos, and then embryo transfer is performed and two weeks after the transfer, a pregnancy test will be performed.

**Category**

Treatment - Drugs

**2****Description**

Control group: Infertile women referred to the infertility treatment center of Mahdieh Hospital, who are in the cycle of frozen embryo transfer, who receive 2 mg estradiol pills (Aburihan Company) three times a day (every 8 hours) to prepare the endometrium on the third day of menstruation. one number) then a control ultrasound is performed and if the follicle reaches 17 to 22 mm and the endometrium thickness reaches 6 to 7 mm, 100 mg progesterone ampoule (Aburihan company) for 3 days in the case of 3-day and 5-day embryos In the case of 5-day-old embryos, the day is injected, and then embryo transfer is performed, and two weeks later, a pregnancy test is performed.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mahdiyeh hospital

**Full name of responsible person**

Samira Azimi

**Street address**

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran

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mahdiyeh\_hospital@sbm.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Samira Azimi

**Position**

Infertility Fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Samia Azimi  
**Position**  
infertility fellowship  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Samira Azimi

**Position**  
Infertility Fellowship  
**Latest degree**  
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**Other areas of specialty/work**  
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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