

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

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

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.

City

Tehran

Province

Tehran

Postal code

1419943471

Phone

+98 21 23871

Email

info@sbm.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code
1185817311
Phone
+98 21 5506 2628
Email
drazimi48@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samia Azimi
Position
infertility fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
drazimi48@gmail.com

Person responsible for updating data

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
Street address
Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
00989 21 55062628
Email
drazimi48@gmail.com

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