

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the pregnancy outcomes in patients with the polycystic ovarian syndrome in two endometrial preparation method GnRHagonist plus hormone replacement therapy versus hormone replacement therapy frozen embryo transfer cycle

Protocol summary

Study aim

Comparison of the pregnancy outcomes in patients with the polycystic ovarian syndrome in two endometrial preparation method GnRHagonist plus hormone replacement therapy versus hormone replacement therapy frozen embryo transfer cycle

Design

This study is designed as a randomized, phase 3 clinical trial with parallel groups, and a sample size of 124 participants. The randomization method will be the block randomization method

Settings and conduct

The study will be conducted at Arash Women's Hospital on all women undergoing the frozen embryo transfer cycle. Patients who signed informed consent will be randomly divided into two groups. The first group will receive GnRH agonist plus hormone replacement therapy for endometrial preparation. Group 2 will receive hormone replacement therapy. The random allocation and final outcome of the study will be assessed by a person who is unaware of the study process. Also, the statistician will be unaware of the study process

Participants/Inclusion and exclusion criteria

Inclusion criteria: The first or second cycle of embryo transfer; Normal uterine cavity; PCO diagnosis based on Rotterdam criteria and correction (2018); Age 20 to 40 years. Exclusion criteria: Infertility with severe male factor; endometriosis; immunological disease; FSH higher than 10; BMI greater than or equal to 30; Endometrial thickness on the day of transfer is less than 7 mm; History of recurrent miscarriage.

Intervention groups

In the frozen embryo transfer cycle, the first group will receive GnRHagonist plus hormone replacement therapy for endometrial preparation. Group 2 will Receive hormone replacement therapy.

Main outcome variables

The endometrial thickness on the day of transfer, chemical pregnancy, clinical pregnancy, Ongoing pregnancy, abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090526001952N15**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **prospective**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

Registration date

2021-05-22, 1400/03/01

Registrant information

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2021-10-12, 1400/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the pregnancy outcomes in patients with the polycystic ovarian syndrome in two endometrial preparation method GnRHagonist plus hormone replacement therapy versus hormone replacement therapy frozen embryo transfer cycle

Public title

Comparison of the pregnancy outcomes in patients with the polycystic ovarian syndrome in two endometrial preparation method GnRHagonist plus hormone replacement therapy versus hormone replacement therapy frozen embryo transfer cycle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The first or second cycle of embryo transfer Normal uterine cavity PCO diagnosis based on Rotterdam criteria and correction (2018) Age 20 to 40 years

Exclusion criteria:

Infertility with severe male factor endometriosis immunological disease FSH higher than 10 BMI greater than or equal to 30 Endometrial thickness on the day of transfer is less than 7 mm History of recurrent miscarriage

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization list will be prepared by a statistician using the block randomization method (using the site:www.sealedenvelope.com). Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained. Then the treatment will be performed based on the kind of treatment in the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Science

Street address

Vice-Chancellor in Research, Tehran University of Medical Science, near Qods st, keshavarz blvd.

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Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.092

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

Infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

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

Endometrial thickness

Timepoint

On the day of transfer

Method of measurement

transvaginal ultrasound

2**Description**

Chemical pregnancy

Timepoint

14 days after transfer

Method of measurement

Beta HCG Test

3**Description**

Clinical pregnancy

Timepoint

7 weeks of pregnancy

Method of measurement

Transvaginal Ultrasound

4**Description**

Ongoing pregnancy

Timepoint

12 weeks of pregnancy

Method of measurement

Ultrasonography

Secondary outcomes

empty

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

Intervention group: In the HRT group, from the second day of the cycle, he receives 2 mg of estradiol daily and this drug is increased to 6 mg per day in three days. Ten days later, they undergo vaginal ultrasound to check the thickness of the endometrium. If the thickness of the endometrium is greater than 8 mm, injectable progesterone is prescribed and the patient will be a candidate for FET transfer. If the thickness is less than 7 mm, it will be necessary to increase the dose of estradiol and continue treatment with it. The patient undergoes vaginal ultrasound every three days and if the desired thickness does not reach 21 days after the start of the cycle, the cycle will be canceled.

Category

Treatment - Drugs

2**Description**

Intervention group: (Long GnRH agonist + HRT) From day 18-21 of the previous cycle, 0.5 cc of Superfect is injected daily and vaginal ultrasound is performed 10-14 days later. If the endometrial thickness is less than 5 mm and there are no ovarian cysts, estradiol is started like HRT treatment and the agonist dose of GnRH starts with estradiol. It is halved (0.25 cc superfect) and superfect is prescribed until progesterone is started. At the time of progesterone administration, the administration of superfect is discontinued. Injections of estradiol and progesterone will be the same as for the HRT group.

Category

Treatment - Drugs

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

Arash Women's Hospital

Full name of responsible person

Ashraf Moini

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

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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

Tehran 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

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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Position

professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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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