Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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

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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.
City
Tehran
Province
Tehran
Postal code
1417614418
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, inject able 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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Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ashraf Moini
Position
professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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