Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Hormone replacement therapy with mild ovarian stimulation as endometrial preparation protocols for frozen-thawed embryo transfer in polycystic ovarian syndrome

Protocol summary

Study aim

Comparison between the effectiveness of letrozole and hormone replacement therapy in frozen embryo transfer technique in polycystic ovarian syndrome (PCOS)

Design

This is a randomized controlled trial on 130 infertile women with polycystic ovary syndrome (PCOS) who underwent invitro fertilization (IVF) or itracytoplasmic sperm injection (ICSI) and frozen embryo transfer. The eligible patients will be randomly allocated into two groups: stimulated cycle with letrozole and human menopausal gonadotropin (HMG; intervention group) and routine artificial hormonal endometrial preparation (control group). The permuted block randomization will be conducted according to a computer-generated list. The patients' enrolment and assignment to groups will be carried out by a researcher midwife in the clinic. Each patient will participate in the study only once and if she has written consent.

Settings and conduct

The study is conducted in Arash Womens Hospital in Baghdarnia St., Tehran, Iran. PCOS diagnosis is based on the Rotterdam criteria. The physician, the researcher midwife and the patient all are aware of received treatment.

Participants/Inclusion and exclusion criteria

Women with polycystic ovarian syndrome and infertility who are candidate for frozen embryo transfer Inclusion criteria: 1. Age 20-35 years; 2. First or second embryo transfer cycle; 3. Normal uterine cavity Exclusion criteria: 1. Severe male factor; 2. pregestational diagnosis; 3. Severe endometriosis; 4. Concurrent immune disease; 5.Follicle stimulating hormone level > 10 IU/ml; 6. Body mass index >= 30 Kg/m2

Intervention groups

Patients will randomly selected in two groups to receive either (i) estradiol valerate or (ii) concurrent administration of letrozole and Human Menopausal Gonadotropine (HMG) for ovulation induction

Main outcome variables

Number (ratio) of successful pregnany Number (ratio) of abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090526001952N12**
Registration date: **2020-03-30, 1399/01/11**
Registration timing: **retrospective**

Last update: **2020-03-30, 1399/01/11**
Update count: **0**

Registration date

2020-03-30, 1399/01/11

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-09-22, 1398/06/31

Trial completion date

2020-03-19, 1398/12/29

Scientific title

Comparison of Hormone replacement therapy with mild ovarian stimulation as endometrial preparation protocols for frozen-thawed embryo transfer in polycystic ovarian syndrome

Public title

Comparison of two endometrial preparation protocols for frozen-thawed embryo transfer in polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20- 35 Years First or second cycle of embryo transfer Normal uterine cavity

Exclusion criteria:

Severe male factor Patients with pregestational diagnosis Severe endometriosis Concomitant immunologic disease Follicle stimulating hormone more than 10 IU Body mass index equal or more than 30

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Actual sample size reached: **135**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, the gynecologist (fellowship in infertility) and an attending physician (also gynecologist - assistant professor) will be aware of the treatment. Although the patient has been already informed about the study and the treatment arms; however, she will not know about the treatment she received.

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 Sciences

Street address

Baghdarnia St.

City

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Province

Tehran

Postal code

1653915981

Approval date

2020-01-29, 1398/11/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.834

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Number (ratio) of successful pregnancy

Timepoint

40 weeks after study initiation

Method of measurement

Medical examination and ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group will be received estradiol valerate (Aboureihan Co.). On day 3 after LMP, estradiol valerate is administered at the dose of 4 mg and will be increased after 3 days to 6 mg. The patient will be examined after a week. An endometrial thickness of 8 mm or more is optimum for progesterone administration (Cyclogest, Actoverco), otherwise the dose of estradiol will be increased up to 8 mg. If the optimal endometrial thickness is not achieved after 20 days, embryo transfer will be canceled.

Category
Treatment - Drugs

2

Description
Intervention group 2: Patients will receive letrozole (Femara, Novartis; 2.5 mg, b.i.d.) on day 3 after LMP for 5 days. Afterward treatment with HMG (Karma Co.; 75-150 mg, daily) on day 5 - 9 after LMP. Endometrial thickness, follicle size, and LH serum levels are measured frequently and in case of follicle size of 12-13 mm, an LH measurement will be done on next visit. Transvaginal ultrasound will be performed every 3 days, while hormon therapy is continued. An endometrial thickness of 8 mm or more or a follicle size of 20 mm or more is good for HCG (Ronak Daru; 5000 - 10000 IU) administration for ovulation induction. On day 20th, if endometrial Thickness was less than 7 mm the transfer cycle will be canceled regardless of follicle condition.
Category
Treatment - Drugs

Recruitment centers

1

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Sponsors / Funding sources

1

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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information regarding main consequence
When the data will become available and for how long
6 months after paper publication
To whom data/document is available
Researchers in academic institutes
Under which criteria data/document could be used
Systematic review and metaanalysis
From where data/document is obtainable
Dr. Ashraf Moini, Arash Women Hospital, 1653915981, Tehran, Iran Email: hosp_arash@tums.ac.ir
What processes are involved for a request to access data/document
Sending request to principle investigator
Comments