

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 intracytoplasmic 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 pregnancy
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

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

Country

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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

Tehran

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

Email

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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 hormone 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****Recruitment center****Name of recruitment center**

Arash Women Hospital

Full name of responsible person

Dr. Azadeh Hosseini

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2**Recruitment center****Name of recruitment center**

Arash Women Hospital

Full name of responsible person

Dr. Azadeh Hosseini

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

Tehran University of Medical Sciences

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

Dr. Azadeh Hosseini

Position

Fellowship of infertility

Latest degree

Specialist

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)

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