

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Endometrial preparation with or without gonadotropin-releasing hormone agonist for frozen-thawed embryo transfer in patients with polycystic ovarian syndrome

Protocol summary

Study aim

Comparison of live births rate in two method of endometrial preparation for embryo transfer in patients with polycystic ovarian syndrome.

Design

A randomized clinical trial with control group, open label, two arm parallel group design of 212 patients. Randomization is performed using a computer-generated random assignment schedule for each patient. Sealed and numbered envelopes are used to conceal the treatment allocation until randomization.

Settings and conduct

Female infertility Clinic of ROYAN institute.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infertile women with PCOS based on Rotterdam criteria; age 20-37 years. Conditions for not entering the study: Women with hematologic and autoimmune disorders; couples with chromosomal and genetic abnormalities; women with uterine anomalies; women with uterine surgical history; women with endometriosis and adenomyosis; women with hydrosalpinx; women with uterine fibroids; early (day 3) follicular phase follicle stimulating hormone levels ≥ 12 IU/L; severe male factor infertility (azoospermia); surrogate mothers and embryo donation.

Intervention groups

Intervention group: The group of endometrial preparation with gonadotropin-releasing hormone agonist. In the this group, the endometrium of patients for embryo transfer will be prepared through the standard protocol using a gonadotropin-releasing hormone agonist. Control group: The group of endometrial preparation without gonadotropin-releasing hormone agonist. In the this group, the endometrium of patients for embryo transfer will be prepared through the standard protocol using steroid hormone administration without gonadotropin-releasing hormone agonist.

Main outcome variables

Live births rate

General information

Reason for update

Acronym

FET-PCOS

IRCT registration information

IRCT registration number: **IRCT20080831001141N27**

Registration date: **2020-11-22, 1399/09/02**

Registration timing: **retrospective**

Last update: **2020-11-22, 1399/09/02**

Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 7960

Email address

kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-20, 1396/05/29

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

2017-08-20, 1396/05/29
Actual recruitment end date
2018-06-20, 1397/03/30
Trial completion date
2020-06-20, 1399/03/31

Scientific title

Endometrial preparation with or without gonadotropin-releasing hormone agonist for frozen-thawed embryo transfer in patients with polycystic ovarian syndrome

Public title

Endometrial preparation for frozen-thawed embryo transfer in patients with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women with polycystic ovarian syndrome based on Rotterdam criteria Age 20-37 years

Exclusion criteria:

Women with hematologic and autoimmune disorders
Couples with chromosomal and genetic abnormalities
Women with uterine anomalies Women with uterine surgical history Women with endometriosis and adenomyosis Women with hydrosalpinx Women with uterine fibroids Early (day 3) follicular phase follicle stimulating hormone levels ≥ 12 IU/L Severe male factor infertility (azoospermia) Surrogate mothers Embryo donation

Age

From **20 years** old to **37 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **212**

Actual sample size reached: **212**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is designed by epidemiologist using STATA software version 13 and the number of blocks considered is 6. The random allocation list for patients is solely available to the epidemiologist. In order to hide the random allocation process, a total of 212 envelopes are prepared, and only the methodologist has been aware of table of random numbers. When the doctor declared the patient's eligibility, the methodologist provided the doctor with the envelope. The group will be selected and based on the type of group mentioned in the envelope.

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

Ethics Committee of Royan Institute

Street address

Royan Institute, Number 12, East Hafez Avenue, Banihashem Street, Resalat Highway.

City

Tehran

Province

Tehran

Postal code

148- 16635

Approval date

2017-08-15, 1396/05/24

Ethics committee reference number

IR.ACECR.ROYAN.REC.1396.135

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Live birth rate; live birth is defined in which a live fetus is delivered beyond 20 completed weeks of gestational.

Timepoint

Only once; at least 20 weeks after embryo transfer.

Method of measurement

Clinical information.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group of endometrial preparation with gonadotropin-releasing hormone agonist. In this group, the endometrium of patients for embryo transfer

will be prepared through the standard protocol using a gonadotropin-releasing hormone agonist. This group has pituitary suppression prior to steroid hormone administration. Pituitary suppression in patients will be performed using 500 micro-gram suprefact (Buserelin, Sanofi Aventis, Germany) injection per day subcutaneously from day 17 of the menstrual and continued it for 14 days. Then, the dose of suprefact was reduced to 200 micro-gram per day, and the endometrium will be prepared through daily administration of 6 mg of estradiol valerate tablets (Abouryhan Pharmacy Company, Tehran, Iran) for 12 days. When endometrial thickness reached 8 mm or more, 50 mg intramuscular progesterone (Abouryhan Pharmacy Company, Tehran, Iran) daily will be commenced, and suprefact will be stopped. Embryo transfer will be performed at 48 ± 3 hours after progesterone injection for two day embryos and 72 ± 3 hours after progesterone injection for three day embryos.

Category

Treatment - Other

2

Description

Control group: The group of endometrial preparation without gonadotropin-releasing hormone agonist. In this group, the endometrium of patients for embryo transfer will be prepared through the standard protocol using steroid hormone administration without gonadotropin-releasing hormone agonist. This group begins steroid supplementation without prior pituitary desensitization. The endometrium will be prepared through daily administration of 6 mg of estradiol valerate tablets (Abouryhan Pharmacy Company, Tehran, Iran) for 12 days. When endometrial thickness reached 8 mm or more, 50 mg intramuscular progesterone (Abouryhan Pharmacy Company, Tehran, Iran) daily will be commenced. Embryo transfer will be performed at 48 ± 3 hours after progesterone injection for two day embryos and 72 ± 3 hours after progesterone injection for three day embryos.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of ROYAN

Full name of responsible person

Firouzeh Ghaffari

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Royan Institute, Number 12, East Hafez Avenue, Banihashem Street, Resalat Highway.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ROYAN Institute

Full name of responsible person

Parvaneh Afsharian

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pafshar@royaninstitute.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

ROYAN Institute

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

ROYAN Institute

Full name of responsible person

Firouzeh Ghaffari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

ROYAN Institute

Full name of responsible person

Firouzeh Ghaffari

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Clinical study report (published article)

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Available to the public.

Under which criteria data/document could be used

Scientific use by citing the source.

From where data/document is obtainable

Dr. Firehouse Ghaffari Email: ghafaryf@yahoo.com

What processes are involved for a request to access data/document

Request via e-mail

Comments