Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

The comparison of ovulation induction with Clomiphene Citrate, Letrozole and recombinant FSH in patients with polycystic ovarian syndrome

Protocol summary

Study aim
Comparison of live births rate in three method of ovulation induction in patients with polycystic ovarian syndrome.

Design
A randomized clinical trial with control group, open label, three arm parallel group design of 360 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 polycystic ovarian syndrome based on Rotterdam criteria; age 20-37 years; Body Mass Index less than 30 Kg/m2; Total Motile Sperm Counts more than one million and normal morphology more than 4% (Husband). 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 and ovaries surgical history; women with endometriosis and adenomyosis; women with hydrosalpinx; women with uterine fibroids; women with recurrent abortion history.

Intervention groups
1. The group of ovulation induction with recombinant FSH. For patients in this group, ovulation induction begins with the daily administration of 50 international units of recombinant FSH. 2. The group of ovulation induction with Clomiphene citrate. For patients in this group, ovulation induction begins with the daily administration of 50 mg of Clomiphene citrate. 3. The group of ovulation induction with Letrozole. For patients in this group, ovulation induction begins with the daily administration of 2/5 mg of Letrozole.

Main outcome variables
Live births rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080831001141N31**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-23, 1399/10/03**
Update count: **0**

Registration date
2020-12-23, 1399/10/03

Registrant information

Name
Kiandokht Kiani

Name of organization / entity
Royan Institute

Country
Iran (Islamic Republic of)

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+98 21 2230 7960

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of ovulation induction with Clomiphene Citrate, Letrozole and recombinant FSH in patients with polycystic ovarian syndrome

Public title
The three methods of ovulation induction 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 Body Mass Index less than 30 Kg/m2 Total Motile Sperm Counts more than one million and normal morphology more than 4% (Husband)

Exclusion criteria:
Women with hematologic and autoimmune disorders Couples with chromosomal and genetic abnormalities Women with uterine anomalies Women with uterine and ovaries surgical history Women with endometriosis and adenomyosis Women with hydrosalpinx Women with uterine fibroids Women with recurrent abortion history

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: **360**

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 360 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

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Tehran

Postal code
148- 16635

Approval date
2018-04-17, 1397/01/28

Ethics committee reference number
IR.ACECR.ROYAN.REC.1397.003

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 patients in the ovulation induction group with recombinant FSH (r-FSH) will receive 50 IU of r-FSH daily from the third day of the menstrual cycle for 7 days, and a monitoring ultrasound will be performed to determine the ovarian response on the 10th day of the menstrual cycle. If follicles larger than 10 mm are observed, the drug will be continued to achieve 18-mm follicles, but if follicles larger than 10 mm are not observed for 7 days, patients will receive 75 IU of

r-FSH per day, and on the 17th day of the menstrual cycle, a monitoring ultrasound will be conducted to determine the ovarian response. At this time, if follicles larger than 10 mm are observed, the drug will be continued to achieve 18-mm follicles, but if follicles larger than 10 mm are not observed for 7 days, patients will receive 100 IU of r-FSH per day, and on the 24th day of the menstrual cycle, a monitoring ultrasound will be conducted to determine the ovarian response. At this time, if no follicles larger than 10 mm are observed, the ovulation induction cycle will be canceled.

Category

Treatment - Other

2

Description

Control group: The patients in the ovulation induction group with clomiphene citrate (CC) will receive 50 mg of CC daily from the third day of menstrual cycle for 5 days, and a monitoring ultrasound will be performed to determine the ovarian response on the 10th day of the menstrual cycle. If follicles larger than 10 mm are observed, the drug will be continued to achieve 18-mm follicles, but if follicles larger than 10 mm are not observed for 5 days, patients will receive 100 mg of CC per day, and on the 17th day of the menstrual cycle, a monitoring ultrasound will be conducted to determine the ovarian response. At this time, if follicles larger than 10 mm are observed, the drug will be continued to achieve 18-mm follicles, but if follicles larger than 10 mm are not observed for 5 days, patients will receive 150 mg of CC per day, and on the 24th day of the menstrual cycle, a monitoring ultrasound will be conducted to determine the ovarian response. At this time, if no follicles larger than 10 mm are observed, the ovulation induction cycle will be canceled.

Category

Treatment - Other

3

Description

Control group: The patients in the ovulation induction group with letrozole will receive 2.5 mg of letrozole daily from the third day of the menstrual cycle for 5 days, and a monitoring ultrasound will be performed to determine the ovarian response on the 10th day of the menstrual cycle. If follicles larger than 10 mm are observed, the drug will be continued to achieve 18-mm follicles, but if follicles larger than 10 mm are not observed for 5 days, patients will receive 5 mg of letrozole per day, and on the 17th day of the menstrual cycle, a monitoring ultrasound will be conducted to determine the ovarian response. At this time, if follicles larger than 10 mm are observed, the drug will be continued to achieve 18-mm follicles, but if follicles larger than 10 mm are not observed for 5 days, patients will receive 7.5 mg of letrozole per day, and on the 24th day of the menstrual cycle, a monitoring ultrasound will be conducted to determine the ovarian response. At this time, if no follicles larger than 10 mm are observed, the ovulation induction cycle will be canceled.

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?

No

Title of funding source

CinnaGen Company

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

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

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Full name of responsible person

Firouzeh Ghaffari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Firouzeh Ghaffari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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