

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of four methods of ovarian stimulation with GnRH antagonist in patients with polycystic ovarian syndrome

Protocol summary

Study aim

Comparison of live births rate in four method of ovarian stimulation in patients with polycystic ovarian syndrome.

Design

A randomized clinical trial with control group, open label, four arm parallel group design of 120 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 20-38 years; body mass index Less than 30 Kg/m2. 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; severe male factor infertility (azoospermia); women with recurrent abortion history; women with recurrent implantation failure history.

Intervention groups

Intervention groups: 1. The group of minimal ovarian stimulation with recombinant FSH 2. The group of minimal ovarian stimulation with Human Menopausal Gonadotropin Control groups: 1. The group of mild ovarian stimulation with recombinant FSH 2. The group of mild ovarian stimulation with Human Menopausal Gonadotropin

Main outcome variables

Live births rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080831001141N30**

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

Registration timing: **retrospective**

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)

Phone

+98 21 2230 7960

Email address

kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2016-11-12, 1395/08/22

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2019-05-30, 1398/03/09

Scientific title

The comparison of four methods of ovarian stimulation with GnRH antagonist in patients with polycystic ovarian

syndrome

Public title

Mild and minimal ovarian stimulation in patients with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women with polycystic ovarian syndrome based on Rotterdam criteria Age 20-38 years Body Mass Index less than 30 Kg/m²

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
Severe male factor infertility (azoospermia)
Women with recurrent abortion history
Women with recurrent implantation failure history

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

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 8. The random allocation list for patients is solely available to the epidemiologist. In order to hide the random allocation process, a total of 120 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

1

Registry name

مرکز ثبت کارآزمایی های بالینی ایالات متحده امریکا
(WWW.clinicaltrial.gov)

Secondary trial Id

NCT03876145

Registration date

2019-03-15, 1397/12/24

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

2016-10-18, 1395/07/27

Ethics committee reference number

IR.ACECR.ROYAN.REC.1395.82

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 minimal ovarian stimulation with recombinant FSH. In this group, patients will receive 100 mg clomiphene citrate every day from

Day 3 to Day 7 of the menstrual cycle and then will be treated with 150 IU Gonal-f (Follitropin alfa, Merck Serono, Germany) after the seventh day.

Category

Treatment - Other

2

Description

Intervention group: The group of minimal ovarian stimulation with human menopausal gonadotropin. In this group, patients will receive 100 mg clomiphene citrate every day from Day 3 to Day 7 of the menstrual cycle and then will be treated with 150 IU Merional (Highly Purified Menotropin, IBSA, Switzerland) after the seventh day.

Category

Treatment - Other

3

Description

Control group: The group of mild ovarian stimulation with recombinant FSH. In this group, patients that will receive 150 IU Gonal-f daily from Day 3 of the menstrual cycle.

Category

Treatment - Other

4

Description

Control group: The group of mild ovarian stimulation with human menopausal gonadotropin. In this group, patients that will receive 150 IU Merional daily from Day 3 of the menstrual cycle.

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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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

Other

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

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Latest degree
Subspecialist
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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

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