Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of Ovarian Stimulation Cycle Outcome in Medroxy Progesterone Acetate and Gonadotropin Protocol with Antagonist and Gonadotropin Protocol in Polycystic Ovarian Syndrome Patients Undergoing In-Vitro fertilization/ Intracytoplasmic Sperm Injection (IVF/ICSI)

Protocol summary

Study aim
To compare the treatment cycle outcome of two ovarian stimulation protocols, MPA co-treatment with gonadotropin protocol and GnRH antagonist protocol in patients with polycystic ovarian syndrome

Design
A randomized, open lable controlled clinical trial with a parallel group design of 232 patients

Settings and conduct
232 eligible infertile patients with PCOS who will refer to infertility clinic of Royan Institue for infertility treatment and are underwent IVF/ICSI will be entered the study with ethic consideration.

Participants/Inclusion and exclusion criteria
The inclusion criteria including: PCOS as diagnosed by Rotterdam criteria, BMI less than 30kg/m2 and age between 18 to 39 years.The women with significant systemic disease such as renal failure, endometriosis grade 3 or higher, severe male factor infertility, received hormonal treatments in the previous 3 months and those who have contraindications to ovarian stimulation won't be included in the study.

Intervention groups
Patients in the study group will receive rFSH (with or without HMG) at a dose of 150 to 225 IU/day and MPA 10 mg/day from day 3 of menstruation. In the control group, rFSH (with or without HMG) at a dose of 150 to 225 IU/day will be given at a dose of 150 to 225 IU/day from day 3 of menstruation and GnRH antagonist (cetrotide 0.25mg) is administered.

Main outcome variables
Fertiliozation rate; number of retrieved oocytes; quality of MII oocyte; OHSS occurrence; premature LH surge; clinical pregnancy rate

General information

Reason for update
The declaration of completion for the clinical trial

Acronym
IVF/ICSI, BMI, PCOS,TESE-PESA

IRCT registration information
IRCT registration number: **IRCT20080831001141N33**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-10, 1405/03/20**
Update count: **1**

Registration date
2021-01-01, 1399/10/12

Registrant information

Name
Kiandokht Kiani
Name of organization / entity
Royan Institute
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-28, 1398/03/07

Expected recruitment end date
2025-06-11, 1404/03/21

Actual recruitment start date
2020-01-01, 1398/10/11
Actual recruitment end date
2022-11-29, 1401/09/08
Trial completion date
2025-12-21, 1404/09/30

Scientific title
Comparison of Ovarian Stimulation Cycle Outcome in Medroxy Progesterone Acetate and Gonadotropin Protocol with Antagonist and Gonadotropin Protocol in Polycystic Ovarian Syndrome Patients Undergoing In-Vitro fertilization/ Intracytoplasmic Sperm Injection (IVF/ICSI)

Public title
Comparison of Two Ovarian Stimulation Protocols in Polycystic Ovarian Syndrome (PCOS) Patients Undergoing IVF/ICSI
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The major criteria for diagnosis of PCOS are oligo and/or anovulation, clinical or biochemical signs of hyperandrogenism and polycystic ovaries; these criteria are in accordance with the revised 2003 Rotterdam criteria for PCOS Age between 18 to 39 years Body mass Index (BMI) less than 30 kg/m2
Exclusion criteria:
Clinically significant systemic disease such as renal failure Endometriosis grade 3 or higher Received hormonal treatments in the previous 3 months Any contraindications to ovarian stimulation Sever male factor (TESE-PESA)
Age
From **18 years** old to **39 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **232**
Actual sample size reached: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method is designed by epidemiologist using randomization website and the number of blocks considered is 4. As soon as the patient is entered into the study, the treatment code is determined from the randomly generated sequence and a unique identification code is assigned to the patient. Random codes are stored in the main project management unit of the study and are inqueried through the clinical caregiver and the relevant intervention will be applied to the new patient. For this purpose, after determining the patient eligibility, the clinical caregiver, inquiries from the project management unit and announces the patient information and receives the patient's assigned identification and treatment code. Therefore, the clinical caregiver will not be aware of the allocative treatment until the patient is admitted.
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
Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1665659911
Approval date
2019-05-28, 1398/03/07
Ethics committee reference number
IR.ACECR.ROYAN.REC.1398.057

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
Fertilization rate
Timepoint
16-18 hours after sperm insemination or injection
Method of measurement
The ratio between the number of zygotes with two pronucleus and the injected oocytes

Secondary outcomes

1

Description
Quality of retrieved oocytes including GV, MI, MII
Timepoint
Immediately after oocyte puncture
Method of measurement
GV: Germinal vesicle present in the ooplasm; MI: No visible GV in the ooplasm and no first polar body in the perivitelline space; MII: Small perivitelline space containing a single unfragmented first polar body

2

Description
Number of MII oocytes
Timepoint
Immediately after oocyte puncture
Method of measurement
Observation of oocytes that were mature at the time of oocyte collection

3

Description
OHSS occurrence
Timepoint
From puncture to subsequent mensturation
Method of measurement
Classification system according to the Navot scheme, including mild, moderate and severe forms

4

Description
Premature LH surge
Timepoint
During ovarian stimulation until the day of triggering
Method of measurement
Serum LH level of equally or more than 10 mIU or an increase of more than 2.5 times above the basal level

5

Description
Clinical pregnancy
Timepoint
4-6 weeks after embryo transfer
Method of measurement
The observation of gestational sac on ultrasound examination two-three weeks after positive serum βhCG

6

Description
Cumulative live birth rate
Timepoint
Delivery of a live fetus after the 24th week of pregnancy with vital activity
Method of measurement
The sum of live birth events resulting from embryo transfers following an ovarian stimulation cycle performed in the study, divided by the number of patients in each group.

7

Description
The rates of obstetrics complications including gestational diabetes, preeclampsia and preterm birth
Timepoint
20 to 42 weeks of pregnancy
Method of measurement
Diagnosed cases of gestational diabetes, preeclampsia, and preterm labor will be followed up and recorded by a gynecologist during pregnancy in all patients.

8

Description
Neonatal outcomes
Timepoint
At birth and a week later
Method of measurement
The neonatologist will evaluate the gestational age, baby's sex, birth weight, presence of congenital abnormalities, diagnosis of respiratory distress syndrome, and diagnosis of jaundice within the first week of birth. The details regarding the newborn will be documented and monitored through phone follow-ups.

Intervention groups

1

Description
Intervention group: Patients will receive rFSH (with or without HMG) at a dose of 150 to 225 IU/day and MPA 10 mg/day from day 3 of menstruation.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive rFSH (with or without HMG) at a dose of 150 to 225 IU/day from day 3 of menstruation and GnRH antagonist (cetrotide 0.25mg) is administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Center of Royan Institute
Full name of responsible person
Abdolhossein Shahverdi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Parisa Mostafaei

Position
Fellowship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable