Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Administration of methylprednisolone for prevention of ovarian hyperstimulation syndrome in in-vitro fertilization cycles

Protocol summary

Summary

This study is a prospective randomized clinical trial to assess the efficacy of the Methylprednisolone for preventing ovarian hyperstimulation syndrome in IVF cycles. The study population comprises all infertile patients, aged 18-35 years old with diagnosis of polycystic ovarian syndrome that will undergo in-vitro fertilization. In this study all eligible patients will be randomly allocated into two study groups by a computerized randomization method. Treatment group will received 16 mg Methylprednisolone initiated from the first day of stimulation and tapered after the first pregnancy test (day 13 after the embryo transfer). Furthermore, these patients will receive 1 gram IV bolous dose of Methylprednisolone, on the day of egg collection and embryo transfer. Patients in the control group will not receive any treatment with Glucocorticoids. If each group confront with every kind of high risk signs or symptoms, they will undergo other preventional methods such as coasting or gonadotropin withdrawal. The presence of OHSS is defined in accordance with the Golan 5 grade system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806181141N6**
Registration date: **2010-01-04, 1388/10/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-01-04, 1388/10/14

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Administration of methylprednisolone for prevention of ovarian hyperstimulation syndrome in in-vitro fertilization cycles

Public title

Administration of Methylprednisolone in prevention of ovarian hyperstimulation syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 1.Poly Cystic Ovarian Syndrome patients 2.Indication for IVF/ICSI and Long Protocol ovarian stimulation 3.Age<35 4.Basal FSH≥10 5.Normal BMI (20-25) 6.Physical health Exclusion Criteria: 1. Allergy to GnRH analogues, FSH and corticosteroids 2.

presence of heart failure, recent myocardial infarction, Hypertension, Diabetes mellitus, epilepsy, glaucoma, hypothyroidism, hepatic failure, osteoporosis, peptic ulceration, psychosis, or severe affective disorders and renal impairment. 3. Using drugs that have interaction with corticosteroids such as Cyclosporine, Phenobarbital, Phenytoin, Rifampin, Ketoconazole, Aspirin and Anticoagulants (All of these drugs shouldn't be used during recent 2 weeks prior to the study and during corticosteroids consumption)

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **218**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Royan institute

Street address
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City
Tehran

Postal code
19395-4644

Approval date
2009-07-28, 1388/05/06

Ethics committee reference number
88/1030/EC

Health conditions studied

1

Description of health condition studied
Ovarian Hyperstimulation Syndrome

ICD-10 code
O94 , O99

ICD-10 code description
Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description
OHSS occurrence rate

Timepoint
Until 20 days after embryos transfer (ET)

Method of measurement
accordance with the Golan 5 grade system

Secondary outcomes

1

Description
Estradiol concentration

Timepoint
on the day before hCG administration

Method of measurement
laboratory results

2

Description
Retrieved and injected oocytes number and quality

Timepoint
oocyte retrieval day

Method of measurement
embryology results

3

Description
Achieved and transferred embryos number and quality

Timepoint
48-72 hours after oocyte retrieval

Method of measurement
embryology results

4

Description
Chemical pregnancy rate

Timepoint
day 13 after embryo transfer

Method of measurement
laboratory results

5

Description
Clinical pregnancy rate

Timepoint
4 weeks after embryo transfer

Method of measurement
Ultrasound results

6

Description
Implantation rate
Timepoint
4 weeks after embryo transfer
Method of measurement
Ultrasound results

7

Description
Cancellation rate
Timepoint
day 13 after embryo transfer
Method of measurement
patient records

Intervention groups

1

Description
routine treatment for prevention of OHSS
Category
Treatment - Drugs

2

Description
Methylprednisolone 16mg/daily orally, until 5 weeks plus 1 gm IV injection on retrieval and embryo transfer day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Dr.moini
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Sponsors / Funding sources

1

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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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty