# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
Iran (Islamic Republic of)
**Phone**
+98 21 2230 7960
**Email address**
kiandokht.kiani@royaninstitute.org

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

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Royan Institute
**Full name of responsible person**
Dr.Vosough
**Street address**
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran
**City**
Tehran
**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

**Contact**
**Name of organization / entity**
Royan institute
**Full name of responsible person**
Ladan Mohammadi Yeganeh
**Position**
MSc of midwifery
**Other areas of specialty/work**
**Street address**
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran
**City**
Tehran
**Postal code**
19395-4644
**Phone**
+98 21 2356 2307
**Fax**
+98 21 2230 6481
**Email**
ladankh2004@yahoo.com
**Web page address**
www.royaninstitute.org

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Royan Institute
**Full name of responsible person**
Dr. Moini
**Position**
MD
**Other areas of specialty/work**
**Street address**
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran
**City**

Tehran
**Postal code**
19395-4644
**Phone**
+98 212362307
**Fax**
+98 21 2230 6481
**Email**
a_moini@royaninstitute.org
**Web page address**
www.royaninstitute.org

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Royan Institute
**Full name of responsible person**
Dr. Moini
**Position**
MD
**Other areas of specialty/work**
**Street address**
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran
**City**
Tehran
**Postal code**
19395-4644
**Phone**
+98 21 2356 2307
**Fax**
+98 21 2230 6481
**Email**
a_moini@royaninstitute.org
**Web page address**
www.royaninstitute.org

## 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*