

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The efficacy of Cabergoline in preventing ovarian hyper stimulation in ART program

Protocol summary

Summary

In this randomized clinical trial, study preventive description of Cabergoline will be compared with Albumin 20% in high risk women for ovarian hyperstimulation syndrome (OHSS) in 130 women. We use a down regulation protocol with a GnRH agonist (Buserelin acetate) as a long protocol for ICSI/ IVF-ET. The inclusion criteria are the development of 20-30 follicles larger than 12 mm in diameter in sonographic evaluation and retrieval of more than 20 oocytes. The exclusion criteria are coasting cases and age more than 37 years. The patients are allocated using a computerized randomization method into two equal groups after the oocytes retrieval to receive human albumin 20% infusion or Cabergoline tablet (0.5 mg) daily for 6 days 30 minutes after oocytes retrieval. The patients will be evaluated 6 days after ET by ultrasonographic examination for ovarian size and detection of ascites. Incidence and severity of OHSS will be assessed using Golan et al 1989 and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808271141N7**
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

2009-08-23, 1388/06/01

Expected recruitment end date

2010-01-21, 1388/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Cabergoline in preventing ovarian hyper stimulation in ART program

Public title

The efficacy of Cabergoline in preventing ovarian hyper stimulation in ART program

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: risk of developing OHSS, defined by the development of 20-30 follicles larger than 12 mm in diameter and retrieval of more than 20 oocytes, ovarian stimulation with long protocol Exclusion Criteria: Coasting cases, age more than 37 years, previous pelvic surgery, Intramural or submucosal myoma sizes > 5 CM, uterine polyps, Smoking, or alcohol addiction

Age

From **15 years** old to **37 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **130**

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

EC/1020

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 and severity of OHSS in two

groups

Timepoint

6 days after embryos transfer(ET)

Method of measurement

accordance with the Golan 5 grade system

Secondary outcomes

1

Description

pregnancy and early miscarriage rates

Timepoint

5 week after embryo transfer until 12 gestational weeks

Method of measurement

Sonography

Intervention groups

1

Description

Gabergoline tablet (0.5 mg) daily until 6 days after oocytes retrieval

Category

Treatment - Drugs

2

Description

Human albumin 20% infusion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Dr.Tehranejad

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. Vosoogh

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
Arezo Arabipour

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
arezoo.arabipoor@gmail.com

Web page address
www.royaninstitute.org

Person responsible for scientific inquiries

Contact

Name of organization / entity
Royan Institute

Full name of responsible person
Ensieh Tehraninejad MD

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
Tehraninejad@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
Eniseh Tehraninejad

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
Tehraninejad@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