Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Royan Institute

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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.Tehraninejad

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Sponsors / Funding sources

1

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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

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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