

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Infusion of calcium gluconate for Prevention of Ovarian Hyperstimulation Syndrome in IVF cycle

#### Protocol summary

##### Summary

Ovarian hyperstimulation syndrome (OHSS) is the most serious and potentially life-threatening iatrogenic complication associated with ovarian stimulation during Assisted Reproductive Technology (ART) protocols. OHSS typically is a result of ovarian expression of vascular endothelial growth factor (VEGF) which increases vascular permeability. Objective: Effects of calcium in the prevention of ovarian hyperstimulation syndrome in patients undergoing IVF/ICSI. Materials and Methods: 95 high risk infertile women in ivf cycle for OHSS (more than 20 follicles in both ovaries during oocyte retrieval) were randomly divided into two groups. Control group: including 93 women received .5 mg/day dopamine agonist (cabergoline) twice aday at day of HCG injection till 5 days. Intervention group: including 93 women received .5mg/day dopamine agonist (cabergoline) twice aday at day of HCG injection till 5 days and intravenous infusion of 10 mL 10% calcium gluconate in 200 mL 0.9% saline solution on the day of ovum pick-up (OPU) and days 1, 2, and 3 after that. The dosage of hMG used, total number of follicles developed, number of oocytes retrieved, serum E2 concentrations during the luteal phase, development of ascites, number of embryos generated clinical pregnancy rate, results of the IVF-ET cycles and incidence and severity of any OHSS were evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016071428930N1**  
Registration date: **2017-01-05, 1395/10/16**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-05, 1395/10/16

##### Registrant information

###### Name

Maliha Mahmoudinia

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 9878

###### Email address

mahmoudiniam941@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor Of Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-04-01, 1395/01/13

##### Expected recruitment end date

2017-04-02, 1396/01/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Infusion of calcium gluconate for Prevention of Ovarian Hyperstimulation Syndrome in IVF cycle

##### Public title

Effects of calcium in the prevention of ovarian hyperstimulation syndrome in patients undergoing IVF/ICSI

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Patients at high risk of ovarian hyperstimulation : PCO; patients having more than 20 follicles > 12 mm during oocyte retrieval; History of OHSS in previous cycles; Estradiol levels over 2500 on the day of HCG administration. Exclusion criteria: Diabetes ; Hypertension ; Asthma ; Blood pressure and Heart disease.

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **186**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences Ethics Committee

##### Street address

Vice Chancellor Of Research, Mashhad University of Medical Sciences, Mashhad University of Medical Sciences, University Avenue, Mashhad

##### City

Mashhad

##### Postal code

#### Approval date

2016-09-03, 1395/06/13

#### Ethics committee reference number

IR.MUMS.REC.1395.326

## Health conditions studied

### 1

#### Description of health condition studied

ovarian hyperstimulation

#### ICD-10 code

N98.1

#### ICD-10 code description

Hyperstimulation of ovaries

## Primary outcomes

### 1

#### Description

Prevention of OHSS

#### Timepoint

From strat to 2 weeks later

#### Method of measurement

Clinical signs and sonography Transvaginal

## Secondary outcomes

### 1

#### Description

Severity of OHSS

#### Timepoint

From start to 15 days later

#### Method of measurement

Clinical signs and Transvaginal sonography

## Intervention groups

### 1

#### Description

High risk infertile women in ivf cycle for OHSS (more than 20 follicles in both ovaries during oocyte retrieval) were randomly divided into two groups. control group received .5mg/day dopamine agonist (cabergolin) twice aday at day of HCG injection untill 5 days

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group received .5mg/day dopamine agonist (cabergolin) twice aday at day of HCG injection till 5 days and intravenous infusion of 10 mL 10% calcium gluconate in 200 mL 0.9% saline solution on the day of ovum pick-up (OPU) and days 1, 2, and 3 after that.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Milad Infertility Center

##### Full name of responsible person

Malihh Mahmoudinia

##### Street address

Milad Infertility center, Mashhad, Khorasan Razavi

**City**  
Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice Chancellor Of Research, Mashhad University of Medical Sciences

**Full name of responsible person**  
Ardakanian

**Street address**  
Vice Chancellor Of Research, Mashhad University of Medical Sciences, Mashhad University of Medical Sciences, University Avenue, Mashhad

**City**  
Mashhad

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Vice Chancellor Of Research, Mashhad University of Medical Sciences

### 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**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Dr. Nayerreh khadem

**Position**  
professor of gynecology group

### Other areas of specialty/work

**Street address**  
Emam Reza Hospital, Mashhad, Khorasan Razavi

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Dr. Nayerreh khadem

**Position**  
Professor of Gynecology

### Other areas of specialty/work

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### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Maliyh Mahmoudinia

**Position**  
Fellowship Of Infertility

### Other areas of specialty/work

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### Web page address

## 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*