

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of oral calcium effect versus placebo in the prevention of moderate to severe OHSS (ovarian hyperstimulation syndrome) in the high-risk patients for OHSS

#### Protocol summary

##### Study aim

Comparison between oral calcium and placebo in preventing of moderate to severe OHSS in patients at risk of OHSS (ovarian hyperstimulation syndrome)

##### Design

A clinical trial with a control group, based on the society, with the parallel group, one-sided blinded, randomized with 150 patients from September 2017 to September 2018.

##### Settings and conduct

This is a prospective study which was done in Mirza Kochakkhan hospital in Tehran. This study was designed as randomized single blinded (patients were blind and had no information about the intervention group)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Antagonist protocol for ART (Assisted Reproductive Technology) 2- The number of follicles  $\geq 20$  mm is over 20. 3- The plasma estradiol level  $\geq 2500$ pg/ml Exclusion criteria: 1-Patients with endocrine disease. 2- Patients with the systemic disease 3- History of neoplasm. 4- Patients that had the high level of plasma estradiol ( $\geq 6000$ pg/ml). 5- Use of insulin-sensitizing drugs. 6- Patients that were required to cycle cancellation

##### Intervention groups

1- Intervention group: Patients with moderate to severe Ovarian Hyperstimulation Syndrome (OHSS) that received Calcium Carbonate 500mg orally every 12 hours for 5 days after injection of HCG or recombinant HCG 2- Placebo group: Patients with moderate to severe OHSS that received oral placebo orally every 12 hours for 5 days after injection of HCG or recombinant HCG

##### Main outcome variables

1- prevalence mild OHSS between two groups( oral calcium and placebo) 2-prevalence moderate OHSS between two groups( oral calcium and placebo) 3- prevalence sever OHSS between two groups( oral

calcium and placebo)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170417033490N2**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **retrospective**

Last update: **2018-12-05, 1397/09/14**

Update count: **0**

##### Registration date

2018-12-05, 1397/09/14

##### Registrant information

##### Name

Zahra Dehbashi

##### Name of organization / entity

Tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8608 9076

##### Email address

zdehbashi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-12, 1396/06/21

##### Expected recruitment end date

2018-09-22, 1397/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of oral calcium effect versus placebo in the prevention of moderate to severe OHSS (ovarian hyperstimulation syndrome) in the high-risk patients for OHSS

**Public title**  
Evaluation of oral calcium effect in prevention OHSS (ovarian hyperstimulation syndrome) in high-risk patients

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

1- Antagonist protocol for Assisted reproductive technology (ART) 2- ) 2- The number of follicles  $\geq$  20 mm is over 20. 3- The plasma estradiol level  $\geq$  2500pg/ml

**Exclusion criteria:**

1-patients with the endocrine disease as Diabetes mellitus, hyperprolactinemia, Cushing disease, congenital adrenal hyperplasia 2- Patients with the systemic disease as asthma, collagen vascular disease, hypercholesterolemia, cycle cell anemia 3- History of neoplasm 4-The plasma estradiol level is high (over 6000pg/ml). 5- Use of insulin-sensitization drugs 6- Patients that were required to the need to cycle cancellation.

**Age**  
From **16 years** old to **45 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **150**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization with random statistics

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, simple randomization method is used and the patients had no information about the types of drug (calcium or placebo), but the nurses and doctors had full information about the types of drug.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee's Tehran university of medical sciences

**Street address**

Buiding (N:1),The Northern Gate of university,Poursina Ave, Ghods Ave, Enghelab St,Tehran,Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

141

**Approval date**

2017-09-11, 1396/06/20

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1396.3431

## Health conditions studied

### 1

**Description of health condition studied**

OHSS(ovarian hyperstimulation syndrome)

**ICD-10 code**

N97.0

**ICD-10 code description**

Female infertility associated with anovulation

## Primary outcomes

### 1

**Description**

Prevention of ovarian hyper stimulation syndrome

**Timepoint**

7 to 14 days after administration of drug

**Method of measurement**

physical exam, transvaginal sonography and blood exam

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Patients with moderate to severe Ovarian Hyperstimulation Syndrome (OHSS) that received Calcium Carbonate 500mg orally every 12 hours for 5 days after injection of HCG or recombinant HCG

**Category**

Prevention

## 2

### Description

Control group( Placebo group): Patients with moderate to severe OHSS that received oral placebo orally every 12 hours for 5 days after injection of HCG or recombinant HCG

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yas hospital

##### Full name of responsible person

Zahra Rezaee

##### Street address

Yas hospital, Fourth alley corner, North Ostad Nejatollahi Avenue, Karimkhan street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

141

##### Phone

+98 21 8608 9076

##### Email

zhrrezaee@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammadali Sahraeian

##### Street address

Research Department, Floor(No:6), Central building of university, Around the corner of Ghods Av, Keshavarz Buld, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

141

##### Phone

+98 21 6670 6142

##### Email

msahrai@sina.tums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tehran University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Zahra Dehbashi

##### Position

Graduated student of infertility fellowship

##### Latest degree

Specialist

##### Other areas of specialty/work

Reproductive Health

##### Street address

Yas hospital, Fourth alley corner, North Ostad Nejatollahi Avenue, Karimkhan street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

41

##### Phone

+98 21 4216 0000

##### Email

zddoctor1390@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Zahra Rezaee

##### Position

Faculty member

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Reproductive Health

##### Street address

Yas hospital, Fourth alley corner, North Ostad Nejatollahi Avenue, Karimkhan street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

41

**Phone**

+98 21 4216 0000

**Email**

zhrrzeae@yahoo.com

**Phone**

+98 21 4216 0000

**Email**

zddoctor1390@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Dehbashi

**Position**

Graduated student of infertility fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Reproductive Health

**Street address**

Yas hospital, Fourth alley corner, North Ostad  
Nejatollahi Avenue, Karimkhan street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

41

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available