Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥ 20 mm is over 20. 3- The plasma estradiol level ≥ 2500pg/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 (≥6000pg/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 ≥ 20 mm is over 20. 3- The plasma estradiol level ≥ 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 Nejatolahi Avenue,Karimkhan street,Tehran,Iran

City
Tehran

Province
Tehran

Postal code

41

Phone

+98 21 4216 0000

Email

zhrrezaee@yahoo.com

Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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Email

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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