Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Calcium infusion and Hydroxyethyl starch infusion in prevention of ovarian hyperstimulation syndrome in high risk women

Protocol summary

Study aim

Comparing the effects of intravenous injection of calcium and hydroxyethyl starch to prevent ovarian hyperstimulation syndrome(OHSS) in high-risk women

Design

This study was done on 100 OHSS high-risk women with the age of less than 35 yrs., low weighted, polycystic ovaries (PCO) tested under ultrasound, history of OHSS and without chronic ovulation accompanied with hyperandrogenism undergone IVF and ICSI referred to infertility centers of Isfahan during 2014-15. If the patient has a history of uterine surgery, a submucosal or intramural myoma of uterus larger than 5 cm or a known kidney or liver disease or who discontinued participating in the project, she would be excluded. The patients were randomly divided into two groups and the first group was administered 100 mg normal saline with 10 mg of 10% calcium gluconate within 2 hours and it was repeated on the second and third days of oocyte removal. In the second group in a time of removing oocyte, 500cc of HES was administered by infusion and it was repeated on the second and third day of oocyte removal. Five days after embryo transfer, the sonographic examination was done for all patients in terms of OHSS findings such as the ovaries size, development of ascites and determination of OHSS intensity. Finally, patients were followed up for 3 months after receiving medications on the incidence of OHSS symptoms or pregnancy and if OHSS happened the intensity was recorded.

Settings and conduct

This study will be done at the Moshtagh infertility center and the infertility center of Shahid Beheshti hospital in Isfahan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having OHSS high-risk Age of less than 35 yrs. Low weighted polycystic ovaries (PCO) tested under ultrasound chronic anovulation accompanied with hyperandrogenism History of OHSS Exclusion criteria With history of uterine surgery With a submucosal or intramural myoma of uterus larger than 5 cm With a known kidney or liver disease Refusal to cooperation in the study

Intervention groups

Injecting calcium or hydroxyethyl starch intravenously

Main outcome variables

The incidence of ovarian hyperstimulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N22**
Registration date: **2018-02-10, 1396/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**
Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

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Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

this study is done based on medical theses and done with financial support of research faculty of medical school of Isfahan university of medical sciences

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Calcium infusion and Hydroxyethyl starch infusion in prevention of ovarian hyperstimulation syndrome in high risk women

Public title
Comparison effect of Calcium and Hydroxy ethyl starch injection on prevention of ovarian hyperstimulation syndrome
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
tested under transvaginal sonographic examination followed by ovulation stimulation protocols there have been more than 18 follicular with the size of more than 12 mm patients agreement for entere to the study
Exclusion criteria:
History of uterine surgeries existence of Sub mucusal or intra mural myoma greater than 5 cm History of hepatorenal diseases
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
100 patients with inclusion criteria will selected and blocked randomly alocated in to two groups of 50
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
Ethic committee of Isfahan university of Medical Sciences
Street address
Soffeh st. Azadi Sq, Isfahan
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Isfahan
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Isfehan
Postal code
8174673461
Approval date
2015-12-09, 1394/09/18
Ethics committee reference number
IR.MUI.REC.1395.167

Health conditions studied

1

Description of health condition studied
ovarian hyper stimulation syndrome
ICD-10 code
E28.1
ICD-10 code description
Hypersecretion of ovarian androgens

Primary outcomes

1

Description
Number and follicle size
Timepoint
every 3 days
Method of measurement
sonographic

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intravenous injection of calcium gluconate 10% (dose: 10 mg with 100 cc normal saline) (Sina Darou Co. IRAN)
Category
Treatment - Drugs

2

Description
Intervention group 2: Intravenous injection of Hydroxy

ethyl starch (dose: 500 cc)(Samen Co. IRAN)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Shahid Beheshti Hospital of Isfahan

Full name of responsible person

Afshan Farshadmehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Isfahan university of Medical sciences

Full name of responsible person

Dr. Mansour Siavash

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Grant name

1234

Grant code / Reference number

395167

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

Yes

Title of funding source

Deputy of Research, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

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Position

Representative of Research

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available