Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of coasting with cabergoline administration for prevention of early severe Ovarian Hyper Stimulation Syndrome in Assisted Reproductive Technology cycles

Protocol summary

Summary
We aim to compare coasting and Cabergoline administration in clinical pregnancy rate and prevention of severe Ovarian Hyper Stimulation Syndrome (OHSS). Materials and Methods: A total of 60 patients with In Vitro Fertilization (IVF)/Intra Cytoplasmic Sperm Injection (ICSI) cycles who are at risk of developing OHSS are selected. The definition of risk is: the presence of pre- ovulatory follicles ≥ 20 in both ovaries. Patients will be divided into two groups randomly. For 30 patients in coasting group, exogenous gonadotropins will be withheld to allow E2 to decrease while GnRH-a will be maintained. Then 10,000 Unit hCG will be administrated and oocyte retrieval will be performed 36 hours later. In Cabergoline group, for 30 patients, hCG will be administered and they receive 0.5 mg per day cabergoline orally from the day of hCG for 8 days. Luteal phase will be supported by administration of progesterone in oil 100mg per day for 14 days. In this study implantation rate, clinical pregnancy rate and incidence of Severe OHSS will be compared in both groups

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT138706091132N1**
Registration date: **2008-12-25, 1387/10/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2008-12-25, 1387/10/05

Registrant information

Name
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Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Research Deputy of Yazd University of Medical Sciences.

Expected recruitment start date
2006-07-01, 1385/04/10
Expected recruitment end date
2007-07-01, 1386/04/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of coasting with cabergoline administration for prevention of early severe Ovarian Hyper Stimulation Syndrome in Assisted Reproductive Technology cycles

Public title
Comparison of coasting with cabergoline administration for prevention of early severe Ovarian Hyper Stimulation Syndrome in Assisted Reproductive Technology cycles
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients with In Vitro Fertilization (IVF)/Intra Cytoplasmic Sperm Injection (ICSI) cycles who

are at risk of developing OHSS. The definition of risk is: the presence of pre- ovulatory follicles ≥ 20 in both ovaries.

Age
From **20 years** old to **38 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

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

1

Registry name

Secondary trial Id

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of Research and Clinical Center for Infertility, Yazd University of Medical Scienc

Street address
Bouali Ave, Safaeyeh

City
Yazd

Postal code
8916877391

Approval date
empty

Ethics committee reference number
1581

Health conditions studied

1

Description of health condition studied
Ovarian Hyperstimulation Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Incidence of Severe OHSS

Timepoint
2 weeks

Method of measurement
Clinical Management

Secondary outcomes

1

Description
Implantation Rate

Timepoint
2 weeks

Method of measurement
Number of gestational sacs per embryo transferred

2

Description
Clinical Pregnancy Rate

Timepoint
2 weeks

Method of measurement
Embryonic cardiac activity observed by ultrasound

Intervention groups

1

Description
In coasting group, exogenous gonadotropins will be withheld to allow E2 to decrease while GnRH-a will be maintained. Then 10,000 Unit hCG will be administrated and oocyte retrieval will be performed 36 hours later. Luteal phase will be supported by administration of progesterone in oil 100mg per day for 14 days

Category
Prevention

2

Description
In Cabergoline group, hCG will be administered and they receive 0.5 mg per day cabergoline orally from the day of hCG for 8 days. Luteal phase will be supported by administration of progesterone in oil 100mg per day for 14 days.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Clinical Center for Infertility, Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person
Abbas Aflatoonian

Street address
Bouali ave, Safaeyeh

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research and Clinical Center for Infertility, Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person
Abbas Aflatoonian

Street address
Bouali Ave, Safaeyeh

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Grant name

Grant code / Reference number

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

Title of funding source
Research and Clinical Center for Infertility, Yazd Shahid Sadoughi 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
Research and Clinical Center for Infertility,Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person
abbas aflatoonian

Position
Head/professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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research consultant/ physician

Other areas of specialty/work

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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