Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of two cabergoline administration methods to prevent ovarian hyperstimulation syndrome (OHSS) in patients with polycystic ovary syndrome (PCO) under IVF

Protocol summary

Study aim
Comparison of the effect of two methods of cabergoline administration to prevent Ovarian hyperstimulation syndrome in patients with polycystic ovary syndrome.

Design
This study is designed as a randomized, single-blind clinical trial with parallel groups with a sample size of 100 individuals per group

Settings and conduct
This clinical trial will be conducted in the infertility department of Arash Hospital. 200 infertile women with PCO who undergo IVF and are at high risk of OHSS will be included in the study. They are randomly assigned to two groups one and two. In the IVF process, in group one,tablets cabergoline(0.5 mg) are prescribed orally and daily for 15 days at the same time as the GNRH antagonist is started, and in group two, in the IVF process, tablets cabergoline (0.5 mg) are prescribed at the same time as the trigger (GNRH agonist) is started. It is prescribed orally for 8 days. IVF process will be done for both groups. From three days after ovarian puncture, clinical and laboratory symptoms and ultrasound examination are performed to check OHSS. The outcome examiner will be unaware of the type of intervention. But the patient will be aware of the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 18-45 patients, with polycystic ovary syndrome, high AMH and AFC Exclusion criteria: sensitivity to cabergoline, not taking the drug completely, discontinuation of the drug due to side effects or drug sensitivity

Intervention groups
Intervention group 1: Simultaneously with the start of GNRH antagonist, half a milligram of cabergoline is prescribed for 15 days Intervention group 2: In this group, at the same time as the trigger (GNRH agonist) begins, half a milligram of cabergoline is prescribed for 8 days.

Main outcome variables
Ovarian hyperstimulation syndrome

General information

Reason for update
The inclusion criteria for AFC and AMH were not precisely defined. High AFC means the number of antral follicles above 20, and AMH means the serum level of antimullerin hormone above 3ng/ml. Also, the secondary outcomes of the study were not registered, which was added to the list of secondary outcomes.

Acronym

IRCT registration information
IRCT registration number: **IRCT20090526001952N16**
Registration date: **2023-05-30, 1402/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-07, 1402/07/15**
Update count: **1**

Registration date
2023-05-30, 1402/03/09

Registrant information

Name
Ashraf Moini

Name of organization / entity
Tehran University of Medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10
Expected recruitment end date
2023-11-21, 1402/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of two cabergoline administration methods to prevent ovarian hyperstimulation syndrome (OHSS) in patients with polycystic ovary syndrome (PCO) under IVF

Public title
Comparison of the effect of two methods of cabergoline administration to prevent ovarian hyperstimulation syndrome in women with polycystic ovary syndrome
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age range of 18 to 45 years old Patients with polycystic ovary syndrome high level of anti-müllerian hormone (AMH) level (> 3 ng/ml) and/or high antral follicle count (AFC)>20
Exclusion criteria:
Allergy to cabergoline Not taking the drug completely Stopping the drug due to side effects or drug sensitivity
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Our sample size is 200 people, with 100 people in each group. The randomization method used in this study will be the block randomization method developed by the statistics expert by using the STATA software in a randomization list format. Then, according to the randomization list, the type of intervention for each individual will be written on paper, and the paper will be put in a sealed envelope. Envelopes will be numbered according to the randomization list. The physician will examine the patient's eligibility, and if the patient is eligible, she will tell the hospital research assistant. The research assistant will then provide the sealed envelope to the physician, and the physician will begin the intervention according to the contents of the envelope.or.
Blinding (investigator's opinion)
Single blinded
Blinding description
Because of the kind of intervention, The patient will be aware of the treatment. Outcomes assessor will not be informed about the kind of treatment A statistician who is unaware of the type of interventions in each group will analyze the data
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Vice-Chancellor in Research Affairs-Tehran University of Medical Science, 6th floor, near Qods st, keshavarz blvd.
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Tehran
Province
Tehran
Postal code
1417614418
Approval date
2023-02-27, 1401/12/08
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.806

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Ovarian hyperstimulation syndrome
Timepoint
Three days after pancture

Method of measurement
Ultrasound and clinical findings

Secondary outcomes

1

Description
Checking the hematocrit level
Timepoint
Three days after ovum-pick up day
Method of measurement
5 cc of blood is drawn in fasting state and the hematocrit level will be measured in Arash Hospital's laboratory with the (Counter SYSMEX KS-500i) device, and the device is calibrated every morning by the responsible expert.

2

Description
Abdominal circumference
Timepoint
Three days after ovum-pick up day
Method of measurement
The abdominal circumference is measured at the midpoint of the line between the rib or costal margin and the iliac crest in the midaxillary line by using tape measure.

3

Description
Patient’s satisfaction
Timepoint
2 weeks after ovum-pick up day
Method of measurement
Patient satisfaction is assessed with a verbal scale of poor, satisfactory, good via telephone call.

4

Description
Serum creatinine level
Timepoint
Three days after ovum-pick up day
Method of measurement
5 cc of blood is drawn in the fasting state and and the level of serum creatinine will be measured in the laboratory of Arash hospital using the Hitachi 717 device and the Jaffe’s method.

5

Description
Serum sodium and potassium levels
Timepoint
Three days after ovum-pick up day
Method of measurement
5 cc of blood is drawn in fasting state and the serum levels of sodium and potassium will be measured in the laboratory of Arash Hospital using the Automatic Electrolyte analyzer of AUDICOM company and the ion selective electrode (ISE) method.

Intervention groups

1

Description
Intervention group1: At the same time as starting the GNRH antagonist, cabergoline 0.5 mg tablets (Aborihan Pharmaceuticals, Iran) are administered orally once a day for 15 days.
Category
Treatment - Drugs

2

Description
Intervention group2:In this group, at the same time as the trigger (GNRH agonist) begins, abergoline 0.5 mg tablets (Aborihan Pharmaceuticals, Iran) are administered orally once a day for 8 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women’s Hospital
Full name of responsible person
Ashraf Moini
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Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr.Fotohi
Street address
Unit 601, Sixth floor, Keshavrz Blvd., Ghods Ave., Tehran University of Medical Sciences
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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
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
Ashraf Moini
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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