

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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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 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, cabergoline 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Fotohi

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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
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Latest degree
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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