

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the efficacy of repeated gonadotropin-releasing hormone agonist (GnRH-a) versus adding low dose human chorionic gonadotropin (HCG) for ovulation induction in patients with polycystic ovary syndrome undergoing IVF/ICSI

Protocol summary

Study aim

Assessment of the efficacy of repeated gonadotropin-releasing hormone agonist (GnRH-a) versus adding low dose human chorionic gonadotropin (HCG) for ovulation induction in patients with polycystic ovary syndrome undergoing IVF/ICSI

Design

This study is designed as a randomized, phase 3 clinical trial with parallel groups, and a sample size of 60 participants. The randomization method will be the block randomization method.

Settings and conduct

This RCT will be conducted at Arash women's Hospital on women with infertility and PCOS. Eligible patients will be divided into two groups after obtaining informed consent. A transvaginal ultrasound will be performed on the second or third day of the menstrual cycle. Ovulation induction will be performed using the rFSH drug at a dose of 150-225 units. After 5 days, if the dominant follicle size is more than 12 mm, 0.25 mg GnRH antagonist will be injected every day. Follicle growth will be monitored by vaginal ultrasound. triggering will be performed if there are at least three dominant follicles (≥ 17 mm). Type of triggering depends on whether the patient is in group A or B. Both groups will undergo oocyte pick up 34 to 36 hr later. Due to the patient's knowledge of the type of intervention performed, it is not possible to blind the patient.

Participants/Inclusion and exclusion criteria

Infertile women with PCOS who are aged 18-38 years old and have normal BMI, normal uterine cavity will be included. History of repeated implantation failure, Endocrinopathies, intaking OCP, and use of TESE or PESA are the exclusion criteria.

Intervention groups

Group A: Subcutaneous injection of 0.2mg Decapeptyl

ampoule (GnRH-a) that will be repeated with a half-dose after 12 hr Group B: Subcutaneous injection of 0.2 mg Decapeptyl ampoule (GnRH-a) with 2000 units of HCG ampoule

Main outcome variables

Rate of OHSS, number of oocytes, M II oocytes, and embryos

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110731007165N8**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Ladan Kashani

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

2019-12-31, 1398/10/10

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of repeated gonadotropin-releasing hormone agonist (GnRH-a) versus adding low dose human chorionic gonadotropin (HCG) for ovulation induction in patients with polycystic ovary syndrome undergoing IVF/ICSI

Public title

repeated gonadotropin-releasing hormone agonist (GnRH-a) versus low dose human chorionic gonadotropin (HCG)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged between 18-38 years old Body mass index below 30 and above 19 kg/m² Normal uterine cavity Ovulation induction by GnRH antagonist cycle regimen

Exclusion criteria:

Repeated implantation failure WHO 1 group Using Percutaneous Epididymal Sperm Aspiration (PESA) or testicular sperm extraction (TESE) History of taking oral contraceptive pills for more than three months before the IVF Endocrinopathies

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistician will divide eligible participants into two groups by using block randomization method. The size of the blocks in this study will be six. The randomization tool used in this study is sealed envelopes that will be prepared by the statistician.

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd, Tehran, Iran

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1417653761

Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.493

Health conditions studied**1****Description of health condition studied**

Infertility associated with polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Ovarian hyperstimulation syndrome (OHSS)

Timepoint

At the end of the study

Method of measurement

Hospital records

2**Description**

Metaphase II (MII) oocytes

Timepoint

At the end of the study

Method of measurement

Hospital records

3**Description**

Total Number of oocytes

Timepoint

At the end of the study

Method of measurement

Hospital records

4**Description**

Number of embryos

Timepoint

At the end of the study

Method of measurement

Hospital records

Secondary outcomes**1****Description**

Endometrial thickness

Timepoint

At the time of embryo transfer

Method of measurement

Vaginal Ultrasound

2**Description**

Embryos quality

Timepoint

At the end of the study

Method of measurement

Hospital records

Intervention groups**1****Description**

First Intervention group (Group A): Subcutaneous injection of 0.2mg Decapeptyl ampoule (GnRH-a) that will be repeated with a half-dose after 12 hr

Category

Treatment - Drugs

2**Description**

Second Intervention group (Group B): Subcutaneous injection of 0.2 mg Decapeptyl ampoule (GnRH-a) with 2000 units of HCG ampoule

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash women's hospital

Full name of responsible person

Dr.Ladan Kashani

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No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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Web page address<http://arash.tums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address<http://vcr.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

Arash Women 's Hospital

Full name of responsible person

Dr. Mahdiyeh Sadat Portabatabaei

Position

Obstetrics and Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Position

Associate professor

Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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Phone

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