

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of Gh on pregnancy outcome of PCO patients candidate for IVF

Protocol summary

Study aim

The effect of Gh on pregnancy outcome of PCO patients candidate for IVF

Design

Two arm parallel groups randomised trial with blinded postoperative care and outcome assessment.

Settings and conduct

This randomized blinded study will be conducted on PCO patients who are candidates for IVF in Yas hospital, the care provider and analyser are blinded.

Participants/Inclusion and exclusion criteria

One hundred patients candidate for IVF Inclusion critria: PCO, age:20-40y Exclusion criteria:history of diabetes, brain tumors

Intervention groups

At second day of cycle Gh plus rFSH will be injected till trigger day Control group: At second day of cycle rFSH will be injected till trigger day.

Main outcome variables

OHSS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N31**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Gh on pregnancy outcome of PCO patients candidate for IVF

Public title

The effect of Gh on pregnancy of PCO patients candidate for IVF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

PCO patients candidate for IVF Susptible to ovarian hyperstimulation

Exclusion criteria:

Pathologic lesion in endometrial cavitypathologic User of corticosteroids or glucose control agents Liver disease Severe male infertility

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Random allocation rule: At first, on special unmarked papers, 50 A letters and 50 B letters are written. Then all(100) are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly without replacement. Based on the letter written on it, the intended intervention is performed on the patient. In addition, interventions A (Gh injection) or B (control group) are determined by lottery.

Blinding (investigator's opinion)

Double blinded

Blinding description

Only the care provider and data analyser are blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Tehran University of medical sciences

Street address

Deputy of Research, central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

159781597815

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.303

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

Infertility

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

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

Number of Oocytes MII

Timepoint

At OPU day

Method of measurement

Embryologist report

2**Description**

Oocyte numbers

Timepoint

At OPU day

Method of measurement

Embryologist report

3**Description**

Ovarian hyperstimulation syndrome

Timepoint

First week after OPU

Method of measurement

History & ultrasonography

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

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Bhcg test

2**Description**

Clinical pregnancy

Timepoint

Four weeks after embryo transfer

Method of measurement

Four weeks after embryo transfer

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

Intervention group:At second day of cycle Gh 10 unit subcutaneous daily will be injected plus rFSH till trigger day.

Category

Treatment - Drugs

2**Description**

Control group: At second day of cycle rFSH will be injected till trigger day.

Category

Treatment - Drugs

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

Yas hospital

Full name of responsible person

Fatemeh Davari Tanha

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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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

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome

When the data will become available and for how long

After publishing article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

After requesting author every statistical analysis is allowed.

From where data/document is obtainable

Dr.Davari, Fatedavtanha@gmail.com

What processes are involved for a request to access data/document

Requesting by email

Comments