Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 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
+98 21 8831 3955
Email address
fdavaritanha@sina.tums.ac.ir

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 size
Target 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
Street address
North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street
City
Tehran
Province
Tehran
Postal code
159781597815
Phone
+98 21 8880 0115
Email
Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Deputy of Research, central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
159781597815
Phone
+98 21 8889 7761
Email
afotouhi@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
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
Street address
North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street
City
Tehran
Province
Tehran
Postal code
159781597815
Phone
+98 21 8880 0115
Email
Fatedavtanha@gmail.com

Person responsible for scientific 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
Street address
North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street
City
Tehran
Province
Tehran

Postal code
159781597815
Phone
+98 21 8880 0115
Email
Fatedavtanha@gmail.com

Person responsible for updating data

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
Street address
North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street
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Tehran
Province
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159781597815
Phone
+98 21 8880 0115
Email
Fatedavtanha@gmail.com

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 ffor 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