

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of recombinant hCG with recombinant hCG plus GnRH agonist for triggering ovulation in ICSI Cycles of poor responder endometriotic patients

#### Protocol summary

##### Study aim

Comparison of r hCG with r hCG plus GNRH agonist for triggering ovulation in poor responder endometriotic patients candidate for ICSI cycles at Yas hospital

##### Design

A placebo-controlled, not blind clinical trial, phase 3, 200 patients, randomized using rand function of Excel software.

##### Settings and conduct

Patients who refer to Yas IVF clinic candidate for ICSI will receive gonadotropin for induction of ovulation and fixed antagonist protocol will be started, induction continued until at least one 18 mm follicle will be occurred at the vaginal ultrasound, then for triggering of ovulation rhCG and placebo in the control group will be injected and in the case group, rhCG plus 0.2 mg GNRH agonist will be injected, 36 hours later oocyte puncture will be performed. Finally, the outcome of the cycle will be evaluated by numbers of MII OOCYTES, good quality embryos, chemical and clinical pregnancy, abortion.

##### Participants/Inclusion and exclusion criteria

Infertile endometriotic patients; AMH <1/1ng/ml; AFC <5; Candidate for IVF

##### Intervention groups

Intervention group 1: r-hCG is injected. Intervention group 2: r-hCG plus two ampoule GnRH\_agonist0.1 is injected.

##### Main outcome variables

Numbers of MII oocytes; Numbers of good quality embryos ;chemical pregnancy ( positive BhCG test); clinical pregnancy ( gestational sac at Transvaginal sonography)

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20091012002576N22**

Registration date: **2022-02-15, 1400/11/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-15, 1400/11/26**

Update count: **0**

#### Registration date

2022-02-15, 1400/11/26

#### 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

2022-02-04, 1400/11/15

#### Expected recruitment end date

2023-02-04, 1401/11/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of recombinant hCG with recombinant hCG

plus GnRh agonist for triggering ovulation in ICSI Cycles of poor responder endometriotic patients

#### Public title

Comparison of r- hCG with r- hCG plus GnRh- a for poor responder endometriotic patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Infertile endometriotic patients AMH <1/1ng/ml AFC <5 Candidate for IVF

##### Exclusion criteria:

Diabetes Hyperprolactinemia Thyroid disease Congenital adrenal hyperplasia Cushing syndrome PCOS Uterine anomaly RIF Azospermia

#### Age

From **18 years** old to **42 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **200**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation rule: First 100 letters A and 100 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (case group) or B (control group) are determined by a lot.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

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

Yas hospital. S arv Aven., North Nej atollahi Street, Karim Khan Zand Bridge, Villa street, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

15978

#### Approval date

2022-02-09, 1400/11/20

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1257

## 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

Pregnancy

#### Timepoint

BhCG levels two weeks after embryo transfer

#### Method of measurement

BhCG levels mg/ml

## Secondary outcomes

### 1

#### Description

Clinical pregnancy

#### Timepoint

Finding gestational sac at vaginal sonography three weeks after embryo transfer

#### Method of measurement

Numbers of gestational sac at transvaginal ultrasound three weeks after embryo transfer

## Intervention groups

### 1

#### Description

Intervention group: One\_ hundred infertile endometriotic patients who are Candidate for ICSI, will prescribed rhCG plus 0.2 Agonist GnRh for triggering of ovulation

#### Category

Treatment - Drugs

### 2

#### Description

Control group: One\_ hundred infertile endometriotic

patients who are Candidate for ICSI, will prescribed rhCG plus placebo for triggering of ovulation

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

One\_ hundred infertile endometriotic patients who are Candidate for ICSI, will prescribed rhCG for t

**Full name of responsible person**

Dr. Fatemeh Davari Tanha

**Street address**

Yas Hospital- Sarv Ave. North Nejatollahi street, Krim khan hand bridge,Villa street

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**Email**

Fatedavtanha@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mis . Mostofi

**Street address**

Research Deputy - 5th floor. Central building of Tehran university o f medical sciences - chods ave. keshavari Boalvar

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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 of Tehran university of medical sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

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### Contact

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**Full name of responsible person**

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Professor

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**Other areas of specialty/work**

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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