

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)

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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

Ethics 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

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Province

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Postal code

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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 be 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

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

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Full name of responsible person

Mis . Mostofi

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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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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