

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation the effect of growth hormone (Gh) on pregnancy outcome of recurrent implantation failure (RIF) via intrauterine infusion.

Protocol summary

Registration timing: **prospective**

Study aim

Evaluation of pregnancy rate in RIF patients after injection of Gh via intrauterine route.

Design

Randomized double blind clinical trial, with 30 patients who are allocated in each parallel group, This is phase 3 trial that for randomization 30 A and 30 B letters will be enveloped in a pocket, and every patient will choose one letter. Physician who will evaluate the outcome and analyser will be blinded regarding groups.

Settings and conduct

At IVF clinic of Yas hospital this randomized double blinded clinical trial with case (Intra uterine infusion Gh at 6th day of estrogen replacement) and control (after transvaginal sonogram estrogen replacement continues) groups will be conducted by using random allocation method, the physician who will be evaluated the outcome and analyser are blinded regarding groups.

Participants/Inclusion and exclusion criteria

Thirty patients with history of recurrent implantation failure, and having good quality embryo, without uterine anomaly or adhesion, who had no response to routine treatment, will be included in the trial.

Intervention groups

Intervention group: After six days of estrogen therapy, Gh will be injected into uterine cavity by IUI catheter, for RIF. Control group: After six days of estrogen therapy, transvaginal sonogram will be done and estrogen continued for RIF.

Main outcome variables

Chemical and clinical pregnancy

Last update: **2023-10-06, 1402/07/14**

Update count: **0**

Registration date

2023-10-06, 1402/07/14

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

2023-10-12, 1402/07/20

Expected recruitment end date

2024-10-11, 1403/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of growth hormone (Gh) on pregnancy outcome of recurrent implantation failure (RIF) via intrauterine infusion.

Public title

Effect of Gh on pregnancy outcome in RIF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N34**

Registration date: **2023-10-06, 1402/07/14**

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of recurrent implantation failure due to unknown etiology Having good quality mbryo

Exclusion criteria:

User of corticosteroids User of glucose control agents
CNS tumors Uterine malformations Asherman syndrome
Cavity distorting lesions Severe endometriosis Liver
disease Severe male infertility Body mass index(BMI)>30
Uncontrolled hypothyroidism

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At First 30 letters A and 30 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 patients. In addition, interventions A (case group) or B (control group) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluator physician differs from the care provider and analyzer only sees the codes in data sheet and are blinded regarding the groups but patients and care provider(who will done randomization) are not 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

Sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

159781597815

Approval date

2023-08-26, 1402/06/04

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.285

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

Biochemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Beta HCG titer test (blood test)

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Four weeks after embryo transfer

Method of measurement

Heart beat activity by transvaginal sonogram

Intervention groups

1

Description

Intervention group: for thirthy patients, intracavitary growth hormone will be injected by IUI (Intrauterine Insemination) catheter one cm above internal OS cervix, 0.5 cc of Gh(Cinatrop Pen, cinagen company) at the 6th day of esterogen replacement therapy,after transvaginal sonogram.

Category

Treatment - Drugs

2

Description

Control group:At the sixth day of estrogen therapy at 30 patients,vaginal sonogram for evaluating endometrial thickness will be performed and estrogen will be continued.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Fatemeh Davari Tanha

Street address

Yas hospital, North Nejatollahi Avenue, Karim khan
Zand Bridge, Villa Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotouhi

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

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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

Undecided - It is not yet known if there will be 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

Data of primary and secondary outcomes

**When the data will become available and for how
long**

After publishing article

To whom data/document is available

To researchers of this filed

Under which criteria data/document could be used

Writing in the reference list

From where data/document is obtainable

By email

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

Request by mail

Comments