# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 2026

## Evaluation of efficacy of subendometrial Growth hormone injection for FET cycle of RIF patients

### Protocol summary

**Study aim**
Increment of pregnancy rate
**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. Patients and physician who will evaluate the outcome will be blinded regarding groups.
**Settings and conduct**
At IVF clinic of Yas hospital this clinical trial will be conducted, the physician who will be evaluated the outcome is blinded.
**Participants/Inclusion and exclusion criteria**
In 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 trail.
**Intervention groups**
For patients with history of recurrent implantation failure at the time of hysteroscopy for crushing endometrium, Gh will be injected in subendometrium at four points, ant.,post., and lateral walls, then embryo transfer will be performed by routin protocol next cycle.
**Main outcome variables**
Chemical and clinical pregnancy

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20091012002576N30**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

**Registration date**
2023-08-30, 1402/06/08

**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**
Evaluation of efficacy of subendometrial Growth hormone injection for FET cycle of RIF patients

**Public title**
Evaluation of efficacy of subendometrial Gh injection for FET cycle of RIF patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
RIF patients Have good quality embryo Having signed

informed consent

**Exclusion criteria:**

Severe male infertility BMI>30 Uncontrolled hypothyroidism User of corticosteroids User of glucose control agents CNS tumors Uterine malformations Cavity distorting lesion Severe endometriosis Liver disease Asherman syndrome

**Age**

From **20 years** old to **44 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

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**

Patients and physicians whe evaluate the outcome are blinded regarding groups

**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**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

15978

**Approval date**

2023-08-23, 1402/06/01

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1402.244

## 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**

Increase of pregnancy rate

**Timepoint**

Two weeks after embryo transfer

**Method of measurement**

Bhcg titer

### 2

**Description**

Clinical pregnancy

**Timepoint**

Four weeks after embryo transfer

**Method of measurement**

Heart beat activity in transvaginal sonogram

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group": At the time of hysteroscopy in luteal phase under anesthesia, Gh will be injected in subendometrial area of endometrial cavity at four points with needle.

**Category**

Treatment - Surgery

### 2

**Description**

Control group: At the time of hysteroscopy in luteal phase under anesthesia, only endometrial crushing will be performed.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Yas hospital
**Full name of responsible person**
Fatemeh Davari Tanha
**Street address**
IVF ward, Yas hospital, North Nejatollahi, 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**
Sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd
**City**
Tehran
**Province**
Tehran
**Postal code**
159781597815
**Phone**
+98 21 8880 0115
**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**
Yas hospital, North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street
**City**
Tehran
**Province**
Tehran
**Postal code**
159781597815
**Phone**
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**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**
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**Phone**
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**Email**
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## 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
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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**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
SPSS file
**When the data will become available and for how long**
After publishing article
**To whom data/document is available**
To Reserchers
**Under which criteria data/document could be used**
Scientific analysis
**From where data/document is obtainable**
By email
**What processes are involved for a request to access data/document**
Request by email
**Comments**