Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Iran (Islamic Republic of)
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotouhi

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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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Person responsible for updating data

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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