

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of subcutaneous Granulocyte colony stimulating factor (G-CSF) versus placebo on in-vitro fertilization (IVF) results in patients with recurrent implantation failure (RIF): A double-blind, randomized, controlled, clinical trial

Protocol summary

Study aim

to investigate the effectiveness of subcutaneous injection of Granulocyte colony stimulating factor (G-CSF) on In vitro fertilization (IVF) results in patients with recurrent implantation failure (RIF)

Design

two arm, parallel group, double blind, randomized, placebo controlled, phase 3, clinical trial

Settings and conduct

Patients will receive boxes sealed with 10-digit codes and containing the original drug or placebo, and they will not be aware of the type of drug received. The researcher will ensure the blinding of the patients as well as the attending physician. The intervention group will receive G-CSF, and the placebo group will receive normal saline as a subcutaneous injection one hour before embryo transfer. Subcutaneous injection of G-CSF and normal saline will be performed by a nurse who did not participate in the present study and has no knowledge of the research plan.

Participants/Inclusion and exclusion criteria

This study will be conducted on embryo transfer candidates with RIF referred to Hamedan Omid Infertility Center.

Intervention groups

In the intervention group, a single dose of 300 µg G-CSF will be injected subcutaneously, one hour before embryo transfer. In the placebo group, participants will receive the same amount of normal saline injection, subcutaneously, one hour before embryo transfer.

Main outcome variables

In vitro fertilization (IVF) results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230718058835N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Seyed Ehsan Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 920 441 4305

Email address

mousavi.e@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-20, 1402/07/28

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of subcutaneous Granulocyte colony stimulating factor (G-CSF) versus placebo on in-vitro fertilization (IVF) results in patients with recurrent implantation failure (RIF): A double-blind, randomized, controlled, clinical trial

Public title

Effect of Granulocyte colony stimulating factor (G-CSF) on in-vitro fertilization (IVF) results

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 40 years maximum FSH level of 15 IU/ml repeated IVF failure absence of contraindications to receiving G-CSF (active infection, tuberculosis cycle disease, chronic neutropenia, history of malignancy in the past, current malignancy, renal failure, upper respiratory tract infection, congenital fructose intolerance) absence of any systemic diseases (hypertension, diabetes, antiphospholipid syndrome, lupus, thrombophilia and thyroid diseases)

Exclusion criteria:

Insufficient endometrial thickness (minimum 7 mm on the day of HCG injection) hypersensitivity to GCSF diagnosis of Asherman's syndrome diagnosis of polyps and fibroids by hysteroscopy refusal to participate in the study

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

Using balanced block randomization, patients will be assigned to one of the two G-CSF and placebo intervention groups. The randomization sequence will be determined by the R program by a person who does not participate in the present study. The patients will receive the boxes sealed with 10-digit codes, which contain the drug or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and the physician will be blinded to allocation and the principal investigator will ensure the blinding of them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Blvd, Pazhoohesh sq.

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.UMSHA.REC.1402.130

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes

1

Description

chemical pregnancy rate

Timepoint

two weeks after embryo transfer

Method of measurement

serum level of β -HCG

Secondary outcomes

1

Description

clinical pregnancy rate

Timepoint

4-6 weeks after embryo transfer

Method of measurement

Transvaginal ultrasound

Intervention groups

1

Description

Intervention group: Intervention group: Granulocyte Colony Stimulating Factor (G-CSF), 300µg, single dose, subcutaneous, injected one hour before embryo transfer

Category

Treatment - Drugs

2

Description

Control group: placebo, normal saline, 300µg, subcutaneously, one hour before embryo transfer

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Omid Infertility Center

Full name of responsible person

Marzieh Sanouei Farimani

Street address

Omid Building, Safa alley, Jahan Nama St.

City

hamadan

Province

Hamadan

Postal code

6516796198

Phone

+98 81 3820 3300

Email

info@hamedanivf.ir

Web page address

<https://www.hamedanivf.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

Shahid Fahmideh Blvd, Pazhoohesh sq.

City

Hamadan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3131 4058

Fax

Email

Fanavari@umsha.ac.ir

Web page address

<https://research.umsha.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Tabriz University of Medical Sciences

Full name of responsible person

Seyed Ehsan Mousavi

Position

researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Mirzakuchakkhan str, No54

City

Tabriz

Province

East Azarbaijan

Postal code

5166753383

Phone

+98 41 3332 1925

Email

drehsanmousavii@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Seyed Ehsan Mousavi

Position

researcher

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Other areas of specialty/work

General Practitioner

Street address

Mirzakuchakkhan str, No54

City

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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Street address

Mirzakuchakkhan str, No54

City

Tabriz

Province

East Azarbaijan

Postal code

5166753383

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+98 41 3332 1925

Email

drehsanmousavii@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available