Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 GCSF, 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 GCSF 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)
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+98 920 441 4305
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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.
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6516796198
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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.
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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
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Seyed Ehsan Mousavi
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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