

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Efficacy of granulocyte colony-stimulating factor in ICSI patients with repeated implantation failure

Protocol summary

Summary

This study was performed to evaluate the effect of granulocyte colony-stimulating factor (G-CSF) on pregnancy outcome following IVF/ICSI in patients with repeated implantation failure (RIF). 100 patients in three groups are included in this three arm trial. 40 patients in case group who have infusion of GCSF in 48-72 h before embryo transfer or in the day of OPU, 40 patients in control group who have infusion of N/S in the day of OPU, and 20 patients who follow the normal cycle without any intervention. Primary outcome is shown with positive b-hcg test 2 weeks after embryo transfer and secondary outcome is clinical pregnancy which is approved by visualising gestational sac in transvaginal sonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108212576N5**

Registration date: **2011-11-12, 1390/08/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-11-12, 1390/08/21

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

Research deputy center of Tehran University of Medical Sciences

Expected recruitment start date

2011-12-01, 1390/09/10

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of granulocyte colony-stimulating factor in ICSI patients with repeated implantation failure

Public title

Efficacy of granulocyte colony-stimulating factor in ICSI patients with repeated implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria

Patients with RIF, aged 25-40 years, were recruited for this prospective study. RIF was defined as the failure of good quality embryos (grade I or II) to implant after at least 3 cycles of IVF/ICSI in infertile women without thrombophilia and anatomic abnormalities of uterine cavity. Exclusion criteria: patients who have sensitivity to GCSF

Age

From **25 years** old to **43 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

efficacy of GCSF on recurrent implantation failuer

Secondary trial Id

efficacy of GCSF on recurrent implantation failuer

Registration date

2011-08-11, 1390/05/20

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Deputy of research of TUMS - 5th floor of TUMS - Ghods ave-Keshavarz Blvd-

City

Tehran

Postal code

15978

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

14967

Health conditions studied**1****Description of health condition studied**

Recurrent implantation failure

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Intrauterin infusion of GCS-F (300mcg) in day of oocyte pick up

Timepoint

Chemical pregnancy

Method of measurement

Measuerment of B-HCG 14 days after embryo transfer

Secondary outcomes**1****Description**

Clinical pregnancy

Timepoint

5 weeks after LMP

Method of measurement

Gestational sac in transvaginal sonography

Intervention groups**1****Description**

Placebo group: 40 patients who have infusion of N/S in the day of OPU

Category

Treatment - Drugs

2**Description**

Case group: 40 patients who have infusion of GCSF in the day of OPU

Category

Treatment - Drugs

3**Description**

Control group:patients who follow the normal cycle without any intervention

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Women Hospital

Full name of responsible person

Fatemeh Davari Tanha

Street address

Ostad Nejatollahi Shomali ave.-Karimkhan Zand st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research of TUMS

Full name of responsible person

Mis.Khalilpour

Street address

5th floor of Tehran University of Medical Sciences-
Ghods ave- Keshavarz Blvd-

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research of TUMS

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty