Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficay 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 posetive b-hcg test 2 weeks after embryo transfer and secondray outcome is clinical pregnancy which is approved by visualising gestatational 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
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Recruitment status
Recruitment complete
Funding source
Research deputy centere 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
Efficay of granulocyte colony-stimulating factor in ICSI patients with repeated implantation failure

Public title
Efficay 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 thrombophila 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 size
Target 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
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5th floor of Tehran University of Medical Sciences- Ghods ave- Keshavarz Blvd-
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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
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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