

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The efficacy of systemic administration of Granulocyte Colony Stimulating factor (GCSF) in patients with repeated In Vitro Fertilization (IVF) failure, a randomized controlled trial

Protocol summary

Summary

Objectives: The aim of this study is to evaluate the efficacy of systemic subcutaneous GCSF administration on IVF success, implantation, and pregnancy rates, in infertile women with repeated IVF failure. **Design:** multi-centric, prospective, randomized, open label, controlled, trial **Inclusion:** infertile women who had ≥ 2 implantation failure after IVF cycles. **Exclusion:** any systemic illness and having thin (-7mm) endometrium. **Sample Size:** 100 infertile women **The Intervention:** GnRH agonist 0.1mg will be administered subcutaneously once/day starting from 7 days before the next expected period until the third day of the cycle. Then daily subcutaneous injection of 300 IU FSH will be applied for 4 days beginning from the third day of the cycle. On the 6th day of the cycle 150 – 300 IU intramuscular injection of hMG will be administered. Transvaginal sonography will be performed every 1-3 days to evaluate the size of the follicles. When at least 2 follicles reached a minimum of 18 mm diameter 10,000 IU intramuscular injection of hCG would be applied. The participants receive 5mg Prednisolone daily starting from the day of hCG injection until three days following oocyte pickup. Transvaginal oocyte pickup will be performed 36 hours after hCG administration. 1-3 good embryos will be transferred into the uterine cavity. The participants will randomly be allocated in 2 groups. In the intervention group a single dose 300 μg GCSF will be administered subcutaneously one hour before the embryo transfer. Luteal phase support will be carried out using Cyclogest suppository 2 times/day and 80 mg Aspirin daily. Two weeks after the embryo transfer serum $\beta\text{-HCG}$ level is measured for all the participants. Four and six weeks after embryo transfer transvaginal sonography will be performed. **The outcomes:** chemical pregnancy, clinical pregnancy and implantation rates. The outcomes will be assessed based on positive serum $\beta\text{-HCG}$ test and detecting gestational

sac and fetal heart on ultrasound examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503119568N11**

Registration date: **2015-03-26, 1394/01/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Research Deputy of the Tehran University of Medical Sciences

Expected recruitment start date

2015-03-30, 1394/01/10

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of systemic administration of Granulocyte Colony Stimulating factor (GCSF) in patients with repeated In Vitro Fertilization (IVF) failure, a randomized controlled trial

Public title
the effect of systemic GCSF administration in infertile women with repeated IVF failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: 1. age < 40 years 2. having ≥ 2 failed IVF attempts where at least 3 good embryos were transferred 3. the lack of contraindications for GCSF treatment (sickle cell disease, chronic neutropenia, known past or present malignancy, renal insufficiency, upper respiratory infection, pneumonia, and congenital fructose intolerance) 4. not having any systemic disease
Exclusion Criteria: 1. having inadequate thin endometrium (< 7mm) on the day of hCG injection 2. the detection of Asherman's syndrome, fibroids, and polyps in diagnostic hysteroscopy 3. having any medical illness upon enrollment (including hypertension, diabetes, antiphospholipid syndrome, systemic lupus erythematosus, thrombophilia, thyroid disorders) 4. refusing to give an informed consent to participate in the study.

Age
From **18 years** old to **39 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy and Ethics Committee of the Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2013-04-07, 1392/01/18

Ethics committee reference number

10010317

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy

Primary outcomes

1

Description

chemical pregnancy

Timepoint

2 weeks after IVF and embryo transfer

Method of measurement

serum β-HCG level

Secondary outcomes

1

Description

Implantation

Timepoint

4 weeks after IVF and embryo transfer

Method of measurement

transvaginal sonography to detect gestational sacs

2

Description

Clinical Pregnancy

Timepoint

6 weeks after embryo transfer

Method of measurement

detection of gestational sac and fetal heart rate on transvaginal sonography

Intervention groups

1

Description

The Control group: The participants in the control group do not receive any additional treatment before embryo transfer.

Category

Treatment - Drugs

2

Description

The Intervention group: The participants in the intervention group receive a single dose of 300 µgr GCSF subcutaneously one hour before the embryo transfer process.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Department, Shariati Hospital

Full name of responsible person

Dr. Mahdi Sheikh

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Infertility Department, Bahman Hospital

Full name of responsible person

Dr. Zhila Abediasl

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

Omid Infertility Clinic

Full name of responsible person

Dr. Ashraf Aleyasin

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy, Tehran University of Medical Sciences

Full name of responsible person

Dr. Atefeh Nazari

Street address

Tehran University of Medical Sciences, Enghelab street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy, Tehran University of Medical Sciences

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

Maternal Fetal and Neonatal Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdi Sheikh

Position

M.D, Ph.D

Other areas of specialty/work

Street address

Maternal, Fetal and Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital complexes, Keshavarz blvd

City

Tehran

Postal code

Phone

+98 912 848 1663

Fax

Email

mahdisheikh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Infertility, Shariati Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Zhila Abediasl

Position

M.D

Other areas of specialty/work**Street address**

Department of Infertility, Bahman Hospital, Saadat
Abad

City

Tehran

Postal code**Phone**

+98 912 347 1504

Fax**Email**

jablediasl@yahoo.com

Web page address**Street address****City**

Tehran

Postal code**Phone**

+98 912 848 1663

Fax**Email**

mahdisheikh@gmail.com

Web page address**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

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

Maternal, Fetal and Neonatal Research Center,
Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdi Sheikh

Position

M.D, Ph.D

Other areas of specialty/work