

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Impact of intrauterine injection of G-csf on implantation and clinical pregnancy rate in repeated implantation failure

Protocol summary

Summary

The main of this study is to Impact of intrauterine injection of G-csf on implantation and clinical pregnancy rate in repeated implantation failure. In a randomized unit-central clinical trial, 68 patients with recurrent implantation failure referring to infertility clinic of Alzahra Hospital, Tabriz, Iran, will be randomly assigned to two groups' case and control. The main inclusion criterion is to have a history of two or more implantation failure in in-vitro fertilization and age between 18 to 45 years and the main exclusion criterion is occurrence of intolerable adverse effects. Endometrial preparation starts with the Estradiol valerate 4 mg tablet once a day and after three days to 6 mg per day increases. Endometrial thickness is determined by ultrasound after 7 days. progesterone injections administered at a dose of 100 mg daily in achieving endometrial thickness of 8 mm. 8-cell embryo transfer after 3 days and 5 days after blastocyst transfer is done. Before progesterone injection in study group 100 micrograms G-CSF with IUI catheter as infusion intrauterine. Three days after the injection of progesterone transferred embryo transfer with a special catheter with abdominal ultrasound . 100 mg daily intramuscular progesterone for luteal phase support continues. in the patients who are FRESH embryo injected GCS-F 100 mcg with HCG by IUI catheter. BHCG test two weeks after embryo transfer is requested. Vaginal ultrasound done 3 weeks after embryo transfer, if it is positive BHCG. In this study, the primary outcome of successful implantation and clinical pregnancy is considered to be a secondary consequence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042312146N6**

Registration date: **2015-04-28, 1394/02/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-28, 1394/02/08

Registrant information

Name

Laaya Farzadi

Name of organization / entity

Woman's Reproductive Health Research Center of Tabriz

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of intrauterine injection of G-csf on implantation and clinical pregnancy rate in repeated implantation failure

Public title

Impact of intrauterine injection of G-csf on implantation

and clinical pregnancy rate in repeated implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 45-18 , and personal satisfaction; Had two or more failures of implantation Exclusion criteria: patients with a history of uterine surgery; hydrosalpinges; endometriosis; Endometrial polyps; Submucosal myoma; Contraindications G-CSF as:Kidney failure; Chronic Neutropenia;anemia; Cancer; Pneumonia.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

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

Tabriz University of Medical Sciences

Street address

Golgasht Street ,Tabriz University Of Medical Sciences

City

Tabriz

Postal code

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

TBZMED.REC.1394.14

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97

ICD-10 code description

Primary outcomes

1

Description

Implantation rates

Timepoint

Two weeks after embryo transfer

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Two weeks after positive BHCG

Method of measurement

Vaginal ultrasound

Intervention groups

1

Description

In the control group: Endometrial preparation starts with the Estradiol valerate 4 mg tablet once a day and after three days to 6 mg per day increases. Endometrial thickness is determined by ultrasound after 7 days. progesterone injections administered at a dose of 100 mg daily in achieving endometrial thickness of 8 mm. 8-cell embryo transfer after 3 days and 5 days after blastocyst transfer is done.

Category

Treatment - Drugs

2

Description

In the case group: Before progesterone injection in study group 100 micrograms G-CSF with IUI catheter as infusion intrauterine. Three days after the injection of progesterone transferred embryo transfer with a special catheter with abdominal ultrasound . 100 mg daily intramuscular progesterone for luteal phase support continues. in the patients who are FRESH embryo injected GCS-F 100 mcg with HCG by IUI catheter

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital
Full name of responsible person
Dr.Farzadi Laya
Street address
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Web page address

Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Alireza Rashidi
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research,Tabriz 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

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Person responsible for updating data

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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

