

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Efficacy of transvaginal perfusion of granulocyte colony stimulating factor on pregnancy in infertile women with recurrent implantation failure in in vitro fertilization (IVF) cycles: A clinical trial

Protocol summary

Summary

Objective: To evaluate GCSF ability to improve pregnancy rate in women with repeated implantation failure
Design: Randomized clinical trial
Setting and conduct: 90 women referred to Yazd research and clinical center for infertility, 2014- 2015 are studied in 2 groups (n=45).
Inclusion and Exclusion criteria: Women with history of recurrent implantation failure, between 20-45 years old, and history of at least 2 implantation failures are included. Participants with sickle cell disease, chronic neutropenia, history of malignancy, renal failure, congenital fructose intolerance, respiratory infection, endometriosis and sever male factor were excluded.
Intervention: For all of participants, in the second day of menstrual cycle, 150 mg of recombinant human follicle stimulating hormone (Gonal-F) is injected subcutaneously for 5 days. Serial Trans-vaginal sonography is performed to detect the mature follicle (14 mm follicle). Then 0.25 mg GnRH antagonist (Cetrotide) is injected subcutaneously. While three follicles reach to 17mm, 100000 mg HCG is injected. After 36 hours Trans-vaginal Egg retrieval is done under sedation. Then 30ml (300 mg/ml) GCSF is administered by slow Trans-cervical intrauterine infusion in intervention group patients. The ccontrol group will continue their cycle without any intervention. Main outcome measures (variable):
Pregnancy outcomes are assessed based on chemical pregnancy (positive pregnancy test) after 2 weeks and clinical pregnancy (gestational sac and fetal heart on ultrasound examination) 2-3 weeks after positive pregnancy test.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201510086420N15**

Registration date: **2015-12-20, 1394/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-20, 1394/09/29

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

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+98 35182470856

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Recruitment status

Recruitment complete

Funding source

Research and Clinical Center for Infertility, Vice chancellor for Research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of transvaginal perfusion of granulocyte colony stimulating factor on pregnancy in infertile women with recurrent implantation failure in in vitro fertilization (IVF) cycles: A clinical trial

Public title

Efficacy of granulocyte colony stimulating factor on recurrent implantation failure in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women between 20-45 years old referred to Yazd infertility center, history of at least 2 implantation failure. Exclusion criteria: Participants with sickle cell disease, chronic neutropenia, history of malignancy, renal failure, congenital fructose intolerance, respiratory infection, endometriosis and sever male factor

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Women were randomly allocated in two equal groups according to random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Research and Clinical Center for Infertility, Shahid Sadoughi University of Med

Street address

Safaeih, BoAli Av., Research and Clinical Center for Infertility, Yazd, Iran.

City

Yazd

Postal code

-

Approval date

2014-06-23, 1393/04/02

Ethics committee reference number

317

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

2 weeks after

Method of measurement

Embryo transfer

2

Description

Clinical pregnancy

Timepoint

2-3 weeks after positive pregnancy test

Method of measurement

gestational sac and fetal heart on ultrasound examination

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

30ml (300 mgr/ml) GCSF was administered by slow Trans-cervical intrauterine infusion in intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Dr. Maryam Eftekhari

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Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Bouali Ave., Safaeyeh, Yazd, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Clinical Center for Infertility, Vice Chancellor for research, Shahid Sadoughi University

Full name of responsible person

Dr. Maryam Eftekhari

Street address

Central Building of Shahid Sadoughi University of Medical Sciences, 3rd floor, Vice Chancellor, Bahonar Sq., Yazd, Iran.

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and Clinical Center for Infertility, Vice Chancellor for research, Shahid Sadoughi University

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

Research and Clinical Center for Infertility, School of Medicine, Shahid Sadoughi University of Medicine

Full name of responsible person

Dr. Maryam Eftekhari

Position

Gynecologist/Infertility Fellowship (M.D.)

Other areas of specialty/work

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Person responsible for scientific inquiries

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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