Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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
Emberyo 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 Eftekhar

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

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research and Clinical Center for Infertility, Vice Chancellor for research, Shahid Sadoughi Universi

Full name of responsible person
Dr. Maryam Eftekhar

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

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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 Universi

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 Medi

Full name of responsible person
Dr. Maryam Eftekhar

Position
Gynocologist/Infertility Fellowship (M.D.)

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