

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect granulocyte colony stimulation factor (GCSF) versus placebo on implantation among infertile patients who underwent assisted reproductive technology (ART): a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of GCSF versus placebo on implantation among infertile patients who underwent ART Design: a randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to the Infertility Research Center of Fatemeh Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) Infertile; (b) age of 20 to 40 years; (c) having determined factor such as endometriosis, myoma, or Asherman's syndrome. Exclusion criteria: (a) having cycle cell anemia, renal failure, upper or lower respiratory infection, or malignancy; (b) contraindication for pregnancy; (c) weak response rate. Intervention: transvaginal injection of GCSF 300 IU, single dose, 2 or 5 days before embryo transfer plus prescription of OCP for 21 days plus 50 mcg GNRH agonist single dose on the 3rd day of menstrual period and 300 to 450 IU FSH or HMG, single dose, on the 14th day of menstrual period. Control: prescription of OCP for 21 days plus 50 mcg GNRH agonist single dose on the 3rd day of menstrual period and 300 to 450 IU FSH or HMG, single dose, on the 14th day of menstrual period. Primary outcome: diagnosis of gestational sac and observation of embryo by transvaginal ultrasonography 24 days after embryo transfer. Secondary outcome: Nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501049014N52**
Registration date: **2015-01-07, 1393/10/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-07, 1393/10/17

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect granulocyte colony stimulation factor (GCSF) versus placebo on implantation among infertile patients who underwent assisted reproductive technology (ART): a randomized clinical trial

Public title

Effect granulocyte colony stimulation factor (GCSF)

versus placebo on implantation among infertile patients who underwent assisted reproductive technology (ART)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) Infertile; (b) age of 20 to 40 years; (c) having determined factor such as endometriosis, myoma, or Asherman's syndrome. Exclusion criteria: (a) having cycle cell anemia, renal failure, upper or lower respiratory infection, or malignancy; (b) contraindication for pregnancy; (c) weak response rate.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: random assignment of the patients systematically one at a time to intervention and control groups. Blinding: Not blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave Hamadan

City

Hamadan

Postal code

6517838695

Approval date

2014-05-17, 1393/02/27

Ethics committee reference number

P/16/35/9/712

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

diagnosis of gestational sac and observation of embryo

Timepoint

24 days after embryo transfer

Method of measurement

by transvaginal ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

transvaginal injection of GCSF 300 IU, single dose, 2 or 5 days before embryo transfer.

Category

Treatment - Drugs

2

Description

prescription of OCP for 21 days plus 50 mcg GnRH agonist single dose on the 3rd day of menstrual period and 300 to 450 IU FSH or HMG, single dose, on the 14th day of menstrual period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Zahra yazdi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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**

Fatemieh Hospital

Full name of responsible person

Dr Zahra yazdi

Position

Resident of Gynecology

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

Fatemieh Hospital, Pasdaran Ave.

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Fatemieh Hospital

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Dr Marzieh farimani

Position

Gynecologist

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

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Fax**Email**

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Web page address

Person responsible for updating data

Contact

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