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 randomzed 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 Fatemieh 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

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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 randomzed 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
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Full name of responsible person
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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