Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of systemic granulocyte-colony stimulating factor versus placebo on implantation in infertile women: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the systemic granulocyte-colony stimulating factor versus placebo on implantation in infertile women. Design: a single blind randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) being infertile; (b) age of 20 to 40 years. Exclusion criteria: (a) contraindication of pregnancy; (b) secondary infertility due to background disease; (c) infertility because of her spouse; (d) weak response to gonadotropin. Intervention group: Injection of granulocyte-colony stimulating factor 300 IU intramuscularly in deltoid muscle at first day and 48 hours later. Control group: Injection of normal saline intramuscularly in deltoid muscle at first day and 48 hours later. Primary outcome: Assessing the formation of gestational sac by transvaginal ultrasound 3 weeks after intervention. Secondary outcome: Assessing beta human chorionic gonadotropin 10 days after intervention by laboratory test. Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: Patients will be unaware of the type of intervention, but the physician who will examine the patients will be aware of the intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511269014N85**
Registration date: **2015-12-05, 1394/09/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-05, 1394/09/14

Registrant information

Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 1838 0090
Email address
poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of systemic granulocyte-colony stimulating factor versus placebo on implantation in infertile women: a single blind randomized clinical trial

Public title

Effect of systemic granulocyte-colony stimulating factor versus placebo on implantation in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) being infertile; (b) age of 20 to 40 years. Exclusion criteria: (a) contraindication of pregnancy; (b) secondary infertility due to background disease; (c) infertility because of her spouse; (d) weak response to gonadotropin.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: Patients will be unaware of the type of intervention, but the physician who will examine the patients will be aware of the intervention. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2015-11-02, 1394/08/11
Ethics committee reference number
IR.UMSHA.REC.1394.334

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Assessing the formation of gestational sac
Timepoint
3 weeks after intervention
Method of measurement
By transvaginal ultrasound

Secondary outcomes

1

Description
Assessing beta human chorionic gonadotropin
Timepoint
10 days after intervention
Method of measurement
By laboratory test

Intervention groups

1

Description
Injection of granulocyte-colony stimulating factor 300 IU intramuscularly in deltoid muscle at first day and 48 hours later
Category
Treatment - Drugs

2

Description
Injection of normal saline intramuscularly in deltoid muscle at first day and 48 hours later
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Nages Mehrabi
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 Nages Mehrabi
Position
Resident of Gynecology
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
narges.mehrabi95@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fatemieh Hospital
Full name of responsible person
Dr Marzieh Farimani
Position
Gynecologist
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
farimanie@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
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