

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

2015-12-05, 1394/09/14

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

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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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

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

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
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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

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Person responsible for scientific inquiries

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Fatemieh Hospital

Full name of responsible person

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Position

Gynecologist

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Person responsible for updating data

Contact**Name of organization / entity**

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Position

Associate Professor

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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