Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of Intrauterine Injection of Granulocyte Colony-Stimulating Factor (G-CSF) on Pregnancy Rate of Infertile Women Undergoing Intrauterine Insemination (IUI)

Protocol summary

Summary

(1) Objectives: The aim of the current study is to determine the effects of intrauterine granulocyte colony-stimulating factor on pregnancy outcome of those undergoing intrauterine insemination (IUI). (2) Design: Randomized, double-blind, placebo-controlled clinical trial. (3) Setting and conduct: Tertiary reproductive health care center (4) Participants including major eligibility criteria: A total number of 200 infertile women between 20 and 40 years of age will be included. We will exclude those with reactions to prostaglandins and comorbidities such and liver and renal failure. (5) Intervention: All the patients will randomly be assigned to received intrauterine injection of G-CSF (n=100) or normal saline as placebo (n=100) at the day of HCG injection. The ovarian stimulation and IUI protocols will be the same in two groups. (6) Main outcome measures (variables): The endometrial thickness on the days of HCG triggering, pregnancy rate and miscarriage rate will be recorded and compared between two study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212079281N2**
Registration date: **2017-05-06, 1396/02/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

Sedigheh Amooee

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2017-03-10, 1395/12/20

Expected recruitment end date

2017-09-11, 1396/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Intrauterine Injection of Granulocyte Colony-Stimulating Factor (G-CSF) on Pregnancy Rate of Infertile Women Undergoing Intrauterine Insemination (IUI)

Public title

Granulocyte Colony-Stimulating Factor for Intrauterine Insemination (IUI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20 and 40 years; unexplained infertility; candidate for intrauterine insemination (IUI) Exclusion criteria: Allergy to

prostaglandins; medical history of liver disease or renal failure; asthma; pulmonary disorders; glaucoma; contraindication of G-CSF injection such as sickle cell anemia, neutropenia and autoimmune disorders; endometriosis; male infertility; decreased ovarian reserve; Asherman syndrome; diabetes mellitus (DM)

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: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Science

Street address
Shiraz University of Medical Sciences, Zand Avenue

City
Shiraz

Postal code

Approval date
2017-01-23, 1395/11/04

Ethics committee reference number
IR.SUMS.MED.REC.1395.60

Health conditions studied

1

Description of health condition studied
infertile women under mild ovary stimulation and IUI

ICD-10 code
N97

ICD-10 code description
Female Infertility

Primary outcomes

1

Description
endometrial thickness in IUI cycle under mild ovarian stimulation

Timepoint
on the day of HCG triggering

Method of measurement
Measuring endometrial thickness on the day of HCG triggering by vaginal sonography.

Secondary outcomes

1

Description
chemical and Clinical pregnancy or miscarriag

Timepoint
16 days after doing IUI

Method of measurement
Serum beta HCG and transvaginal sonography.

Intervention groups

1

Description
Clomiphene citrate 100 gr QD from 5th -9th day of cycle and gonadotropin (FSH), 50-150 unit will be added in 8th day of cycle till there is one follicle with diameter 18 mm in vaginal sonography and , granulocyte colony-stimulating factor (G-CSF) will be injected intrauterine on the day of HCG injection

Category
Treatment - Drugs

2

Description
Clomiphene citrate 100 gr QD from 5th -9th day of cycle and gonadotropin (FSH), 50-150 unit will be added in 8th day of cycle till there is one follicle with diameter 18 mm in vaginal sonography

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mother & Child Hospital

Full name of responsible person
Zahra Shomali

Street address
Mother & Child hospital, Quran gate

City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
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Shiraz University of Medical Sciences، Zand Street
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Shiraz
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 of Shiraz 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

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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