

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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

##### Country

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##### Phone

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##### Email address

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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 miscarriage

**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

**Street address**

Shiraz University of Medical Sciences, Zand Street

**City**

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

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Zahra Shomali

**Position**

Fellowship Infertility

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## Person responsible for updating data

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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*