

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of granulocyte colony stimulating factor (G-CSF) on IVF outcome and pregnancy rates.

#### Protocol summary

##### Study aim

evaluating the effect of intrauterine infusion of G-CSF on pregnancy rate. study groups are infertile patients

##### Design

A clinical trial with the control group, with parallel groups, not blinded, phase 3 per 100 patients. A random number table was used for randomization.

##### Settings and conduct

This study is performed in Yazd Infertility Research Center. 100 IVF candidate patients are divided into 2 groups using a random table. One group receives the usual antagonist stimulation protocol. In the control group, in addition to the antagonist protocol, 300 micrograms of granulocyte colony-stimulating factor are infused into the endometrial cavity by intrauterine insemination catheter on the day of egg puncture.

##### Participants/Inclusion and exclusion criteria

inclusion : infertile women aged 18-40 years old with normal endometrial thickness who were candidates for IVF  
exclusion : Women with a history of repeated implantation failure , endocrine disorders, severe endometriosis, congenital or acquired uterine anomaly, renal disease, sickle cell disease, or malignancy history, upper respiratory tract infection, pneumonia, chronic neutropenia

##### Intervention groups

Intervention: injection of 300 micrograms G-CSF in the uterine cavity with IUI catheter in oocyte retrieval day  
control: oocyte retrieval will be done 36 hours after HCG triggering and embryos will be transferred 2 days latter.

##### Main outcome variables

chemical pregnancy, clinical pregnancy, Implantation rate, ongoing pregnancy , the miscarriage rate

#### General information

##### Reason for update

Updating exclusion criteria and outcomes according to the last methodological changes

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508236420N13**  
Registration date: **2015-11-07, 1394/08/16**  
Registration timing: **retrospective**

Last update: **2021-08-23, 1400/06/01**

Update count: **1**

##### Registration date

2015-11-07, 1394/08/16

##### Registrant information

###### Name

Maryam Eftekhar

###### Name of organization / entity

Yazd Research and Clinical Center for Infertility

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35182470856

###### Email address

eftekhar@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Science

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2015-09-23, 1394/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of granulocyte colony stimulating factor (G-CSF) on IVF outcome and pregnancy rates.

**Public title**

Effect of granulocyte colony stimulating factor in ART treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

infertile women candidate for IVF normal endometrial thickness age 18-40 years old

**Exclusion criteria:**

repeated implantation failure endocrine disorders severe endometriosis congenital or acquired uterine anomaly renal disease sickle cell disease malignancy history upper respiratory tract infection pneumonia chronic neutropenia

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this trial, infertile women who were scheduled for ART and met the inclusion criteria, informed about the research design and signed a written consent form for random assignment either to case or control groups. All women were randomly divided into two groups using simple, individual through random number table. All women were consecutively assigned into two groups based on randomized list.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Science

**Street address**

Research and Clinical Center for Infertility, Bouali,

Timsar Fallahy, Safayeh, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Approval date**

2015-02-08, 1393/11/19

**Ethics committee reference number**

444

**Health conditions studied****1****Description of health condition studied**

Infertility

**ICD-10 code**

N98.9

**ICD-10 code description**

Complication associated with artificial fertilization, unspecified

**Primary outcomes****1****Description**

chemical pregnancy

**Timepoint**

14 days after embryo transfer

**Method of measurement**

serum  $\beta$ hCG

**Secondary outcomes****1****Description**

ongoing pregnancy

**Timepoint**

10 weeks after embryo transfer

**Method of measurement**

sonography

**2****Description**

abortion

**Timepoint**

18 weeks after embryo transfer

**Method of measurement**

sonography

**3****Description**

clinical pregnancy

**Timepoint**

3 weeks after positive BHCG

**Method of measurement**

sonography

#### 4

##### **Description**

implantation

##### **Timepoint**

3 weeks after positive BHCG

##### **Method of measurement**

assessed by the number of gestational sacs per number of transferred embryos

## **Intervention groups**

#### 1

##### **Description**

In intervention group in oocyte retrieval day, 300 microgram G-CSF ampoul infused in endometrial cavity with IUI catheter immediately after retrieval.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

in control group (50 patients) G-CSF not infused in endometrial cavity.

##### **Category**

Treatment - Drugs

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Shahid Sadoughi University of Medical Science

###### **Full name of responsible person**

Dr.Maryam eftekhar, Associated Professor of Shahid Sadoughi University of medical science

###### **Street address**

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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Vice Chancellor for research of Shahid Sadoughi

University of Medical Sciences

###### **Full name of responsible person**

Abass Aflatounian

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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 of Shahid Sadoughi University of Medical Sciences

###### **Proportion provided by this source**

100

###### **Public or private sector**

Public

###### **Domestic or foreign origin**

Domestic

###### **Category of foreign source of funding**

*empty*

###### **Country of origin**

###### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

##### **Contact**

###### **Name of organization / entity**

Sadoughi University of Medical Science ,Yazd

###### **Full name of responsible person**

Maryam Eftekhar

###### **Position**

Professor

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All participant data sets are to be shared

### When the data will become available and for how long

2 months after the result publication

### To whom data/document is available

Researchers working in academic institutions

### Under which criteria data/document could be used

use in the retrospective study

### From where data/document is obtainable

Yazd research and clinical center for infertility

### What processes are involved for a request to access data/document

Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.

### Comments