

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Evaluation the effect of granulocyte colony stimulating factor on fertility rate in infertile woman with unexplained infertility

#### Protocol summary

##### Study aim

Evaluation the effect of granulocyte colony stimulating factor in infertile woman with unexplained infertility

##### Design

This study is a randomized clinical trial that will be performed on 126 women with unexplained infertility in infertility clinic of Yasouj University of Medical Sciences during 2018-2019.

##### Settings and conduct

All patients eligible for inclusion in the study are treated with letrozole tablets and manotropin injection during the IUI cycle. After ovulation induction on the eleventh day of the menstrual cycle, transvaginal sonography is performed to examine the growth and size of the follicles. In the event of one or two follicles with a size greater than 18 mm, the same day in both groups, injection of HCG ampule are done, and IUI is administered in both groups 36 hours after injection of HCG ampule. Two days after performing IUI in the intervention group, a recombinant human granulocyte colony stimulating factor (GCSF) (300 micrograms) injection is injected subcutaneously. After two weeks from the date of the IUI, patients will be screened for the BHCG test of pregnancy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Unexplained infertility, Endometrial thickness more than 6 mm. Exclusion criteria: Lack of follow-up, Unwillingness to participate in the study, Infertility duration more than 5 year, Age >35 year, Blocked fallopian tubes, Having endocrine disorders, Acquired and congenital uterus anomalies

##### Intervention groups

Administration of granulocyte colony stimulatory factor (300 µg) subcutaneously two days after IUI in comparison with no reception of granulocyte colony stimulus factor

##### Main outcome variables

Fertility rate

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20160524028038N4**

Registration date: **2019-06-03, 1398/03/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-03, 1398/03/13**

Update count: **0**

##### Registration date

2019-06-03, 1398/03/13

##### Registrant information

##### Name

Fatemeh Bazarganipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3366 6367

##### Email address

bazarganipour@hums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-09, 1397/11/20

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluation the effect of granulocyte colony stimulating factor on fertility rate in infertile woman with unexplained infertility

**Public title**

Granulocyte colony stimulating factor on fertility rate

**Purpose**

Treatment

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

Unexplained infertility Endometrial thickness more than 6 mm Age between 15-37 year

**Exclusion criteria:**

Lack of follow-up Unwillingness to participate in the study Infertility duration more than 5 year Blocked fallopian tubes Having endocrine disorders Acquired and congenital uterus anomalies

**Age**

From **15 years** old to **37 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **126**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method is simple. The sealed envelopes were used.

**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 Yasuj University of Medical Sciences

**Street address**

No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7916839319

**Approval date**

2018-12-08, 1397/09/17

**Ethics committee reference number**

IR.YUMS.REC.1397.122

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

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

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

Fertility rate

**Timepoint**

After two weeks from the date of the IUI

**Method of measurement**

BHCG test

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Administration of granulocyte colony stimulatory factor (300 µg) subcutaneously two days after IUI in comparison with no reception of granulocyte colony stimulus factor

**Category**

Treatment - Drugs

**2****Description**

Control group: No receipt of granulocyte colony stimulating factor

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yasuj University of Medical Sciences

**Full name of responsible person**

Fateneh Najafi

**Street address**

No. 7916839319, Shahid Jalil Ave., Yasuj Town,  
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**Phone**

+98 74 3333 7251

**Email**

fataneh.najafi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Hossein Mari-Oriad

**Street address**

No. 7916839319, Shahid Jalil Ave., Yasuj Town,  
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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Fataneh Najafi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Fataneh Najafi

**Position**

Studnet

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available