

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,
Kohgiluyeh and Boyer-ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

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,
Kohgiluyeh and Boyer-ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

fataneh.najafi@yahoo.com

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

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

fataneh.najafi@yahoo.com

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

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

fataneh.najafi@yahoo.com

Person responsible for updating data**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

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

fataneh.najafi@yahoo.com

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