

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of intrauterine administration of granulocyte-colony stimulating factor (GCSF) in IVF cycles on the fertility rate of infertile women suffering from moderate to severe endometriosis

Protocol summary

Study aim

the aim of this study is to examine the effect of intrauterine administration of GCSF in IVF cycles on the fertility rate of infertile women suffering from moderate to severe endometriosis.

Design

The sample size of this study is 66 persons who will be randomly divided into two groups of GSF injection and without intervention. Participant are allocated by computerized list

Settings and conduct

This is a single-blind clinical trial study on 66 infertile women at Arash Hospital. After allocation, the first group receives GSF injection immediately after puncture and the second group has no intervention. Clinical pregnancy is assessed by transvaginal ultrasound 3 weeks after transfer.

Participants/Inclusion and exclusion criteria

The inclusion criteria: fertility due to endometriosis, age 18-40 years, moderate to severe endometriosis Inclusion criteria: male factor infertility, evidence of a significant decrease in the ovarian reserve (FSH>11, AMH<0.5, decreased AFC), endocrine disorders (diabetes, thyroid diseases, hyperprolactinemia, hypothalamic amenorrhea, etc.), confirmed medical and immunologic diseases

Intervention groups

Intervention group: Immediately after ovarian puncture, 300µ GCSF is injected through a transcervical catheter into the uterine cavity Subjects in the control group received no intervention (blank control)

Main outcome variables

Clinical pregnancy

General information

Reason for update

Moderate and severe endometriosis were further

explained. In this study, it was not possible to blind the patient

Acronym

IRCT registration information

IRCT registration number: **IRCT20110731007165N7**

Registration date: **2019-09-10, 1398/06/19**

Registration timing: **retrospective**

Last update: **2021-07-25, 1400/05/03**

Update count: **1**

Registration date

2019-09-10, 1398/06/19

Registrant information

Name

Ladan Kashani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8828 1866

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-15, 1397/10/25

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intrauterine administration of granulocyte-colony stimulating factor (GCSF) in IVF cycles on the fertility rate of infertile women suffering from moderate to severe endometriosis

Public title

Effect of intrauterine administration of granulocyte-colony stimulating factor (GCSF) in IVF cycles on the fertility rate of infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First time IVF due to infertility Moderate to severe endometriosis (according to laparoscopic criteria, moderate endometriosis was defined as Adhesion affecting Fallopian tubes or ovaries, and severe endometriosis was defined as the involvement of Fallopian tubes, ovaries, and cul-de-sac) Age 18-40 years Fertility due to endometriosis Moderate -to -severe endometriosis was characterized by endometrial glands and stroma at least 5 mm beneath the peritoneum or an ovarian endometriotic cyst (endometrioma)

Exclusion criteria:

Male factor infertility. Evidence of a significant decrease in the ovarian reserve (FSH>11, AMH<0.5, decreased AFC), Endocrine disorders (diabetes, thyroid diseases, hyperprolactinemia, hypothalamic amenorrhea, etc.) , confirmed medical and immunologic diseases (SLE, rheumatoid arthritis, antiphospholipid syndrome, cardiovascular, liver, and renal diseases), and congenital uterine anomalies and uterine cavity disorder (bicornuate uterus, unicornuate uterus, Asherman syndrome, myoma, polyps, etc.). Donation candidates (ovum donation and surrogate uterus) were also excluded from the study

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: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 66 people, with 33 people in each group. patients were allocated by simple randomization. In this method RANDBETWEEN function in the Excel program is used to generate a random number between 1 and 2. This is repeated 66 times.

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 Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd, Tehran, Iran

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1417653761

Approval date

2019-01-12, 1397/10/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.787

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

Primary outcomes

1

Description

clinical pregnancy

Timepoint

3 weeks after embryo transfer

Method of measurement

Vaginal ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Immediately after ovarian puncture, 300µ GCSF is injected into the uterine cavity

Category

Treatment - Drugs

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Dr.Ladan Kashani

Street address

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ladan Kashani

Position

Assistant Prof.

Latest degree

Medical doctor

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available