Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

Phone
+98 21 8828 1866

Email address
kashani_ladan@tums.ac.ir

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 utrus) 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

City
Tehran

Province
Tehran

Postal code
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
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Fax
+98 21 7788 3196
Email
Kashani_ladan@tums.ac.ir
Web page address
http://arash.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Sahraean
Street address
Tehran University of Medical Sciences, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
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
Gynecology and Obstetrics
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Person responsible for scientific 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
Gynecology and Obstetrics
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Province
Tehran

Postal code
1653915981
Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ladan Kashani
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash hospital, Tehranpars
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 8828 1866
Fax
+98 21 8895 2510
Email
kashani_ladan@tums.ac.ir

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